12/22/2017

Follow-up Items on AAN Proposal from PRT

The PRT asks the American Academy of Neurology (AAN) - the submitter to respond in writing to the following questions by the end of the 2nd week of January, preferably by Wednesday January 10th. Based on the written responses, the PRT may invite the submitter to respond to any follow-up questions via phone call in late January/early February.

Questions about the Proposed Patient-Centered Headache Model for Submitter

Epidemiology of Headaches and Treatment

1. On page 6, you write that the average cost for a patient visit was more than $4000 across all settings (reference #10, MEPS 2014 Consolidated Conditions). Do you literally mean a single patient visit or total spending that a visit/encounter generated, which might include hospitalizations etc.? We will also review the MEPS reference you cite for this fact if you would kindly send it to us, but also please provide detail of what this $4000 represents.

2. We assume that it is not common for complex pattern headaches to first present when people have aged into Medicare. Is that correct?
    - If so, wouldn't your proposal really only address improved management of already diagnosed (accurately or not) migraine/cluster headache patients?
    - By the time patients enter Medicare, how big a problem is previous misdiagnosis and ongoing mismanagement? In other words, how often would you say a patient who is newly insured by Medicare has been misdiagnosed? And what are some of the wrong diagnoses?

3. Based on the literature, what are important variations in treatment approaches for migraine and cluster headaches based on the specialty and experience of the treating physician, for example, the use of oral medications and opioids, Botox, etc.?
    - Is evidence of different treatment approaches by different types of clinicians important in setting out the objectives of the delivery model you propose? In other words, where there may be opportunities for improving care and reducing use of low-value services.

Care Delivery Model

1. Although most of the proposal seems to be a model for caring for complex pattern headache patients, often on referral, at times it seems to be a more general headache delivery model, such as when the proposal refers to an established "Headache Care Team" and also when it presents a Triage Protocol "to determine which patients need highly specialized headache care," i.e., those with acute, disabling headaches.
    - Please clarify. What patient population – those with headaches or only those with complex pattern headaches would be recipients of the new delivery model?

2. You write on p.2, "This model proposes three distinct categories of care based on stage and complexity of headaches." The proposal indicates the Headache Care Team "includes a neurologist, headache care specialists, primary care physician, a patient care coordinator, nutritionist, physical therapist and/or mental health or social service provider to support patient care". On p4, the proposal states that "low complexity patients would… remain with the primary care physician" for ongoing management under Category 3, with coordination between the PCP and neurologist, however on p10, it states ongoing management in category 3 could be supported by an APP within a neurology practice, rather than a PCP. We do not follow.
    - Please make clear the relevance of the three categories with regard to the provision of care.

3. Please explain the function of the various team members, including the physical therapist, nutritionist, mental health therapist or social worker, specifically in reference to treatment for the ICD-10 conditions listed in Appendix B. These disciplines would seem relevant for a broader headache team, but how are they relevant specifically for complex pattern headaches
    - What is the role of the care coordinator (Appendix A)?
    - How does that role differ from that of the Advanced Practice Provider (described in the proposal on p10 as "non-physician members of the care team, including NPs, PA, certified nurse midwives, clinical psychologists, nonclinical psychologists, clinical nurse specialists")?
    - What are the skills and qualifications of the care coordinator?
    - Who does the patient primarily interact with?

4. The proposal seems to be describing an actual team with a primary care physician included, although at time references virtual teams (p7) across practices.
    - Given that patients with complex pattern headaches presumably present with symptoms across most ambulatory care sites – office practices, emergency rooms, urgent care centers – and see a myriad of primary care practitioners – in the hundreds of thousands -- how can primary care physicians participate on a real team and gain "preferred provider status" as described on p7?
    - Is the model described really a team based within a neurology practice which sees patients on referral from primary care physicians and then provides guidance back to the primary care physician once patients achieve maintenance status?

5. What are the qualifications of the "headache specialist" you refer to?
    - How is that different or equivalent to a neurologist?
    - Does the submitter have any evidence/data to show what should be the minimum standards for designation of a headache specialist ?

6. Are there some prototype models - for either general headache teams or complex pattern headache teams that seem to be the focus of this proposal – being piloted in integrated health systems, such as Kaiser Permanente or large neurology centers?

- What can we learn from their experiences?

7. The Medicare Physician Fee Schedule already pays for a "Welcome to Medicare" initial preventive visit which beneficiaries can take advantage of within the first 12 months of Part B eligibility and as part of "annual wellness visits" with their regular physician.
    - Why wouldn't this serve as adequate triage to assure referral of patients who would benefit from a consultation with a headache specialist for complex pattern headaches?
    - While there is appeal of the model in a younger population, as suggested by our initial questions, it is not clear that this particular delivery model is particularly needed in the Medicare patient population. Please explain.

8. Please describe what is gained from the 20-30 minute "pre-assessment" by the medical assistant or registered nurse (p4) prior to seeing the neurologist for another 30-60 minutes. The sample headache diary template (Appendix E) appears to be weekly information filled out by the patient, not staff.
    - What information does this yield about the patient that improves the quality and efficiency of the process?
    - Can the submitter provide pre-assessment protocols or other materials for the PRT to review?

9. How would this proposed delivery model work in different types of settings - such as rural independent practice vs. a fully integrated delivery system or large urban neurology practice? Please be as specific as possible for each type of setting.

10. There is interest from PRT members to review the Axon registry and its measures. Please provide additional detail with a complete set of measures.

<u>Payment Model</u>

1. The PRT would like to understand what type of patient specifically is the target of this model. Please provide all the criteria for the patient to be eligible and included in the model.
    - Does the patient require a referral from a primary care or ER physician to be included in the model? Is that the trigger for the "predetermined, fixed payment per patient?"

2. The model submitters note that patients have the choice of opting into the program. The PRT assumes that a formal opt-in is needed to trigger the add-on payments in the model.
    - Is that correct?
    - Does the beneficiary give up any freedom of choice of provider at any time during the period when they have opted in?
    - How are payments affected if opt-in patients are actively obtaining care outside of the headache team?
    - What are the advantages and disadvantages of patients opting in?

3. The PRT wants to better understand how the model will likely motivate clinicians to generate cost savings. The proposed monthly payments are larger than current E&M payments.
    - Will there be cost savings to make up the difference?
    - Alternatively, practices that become designated headache centers could take upside and downside risk based on spending performance, but you do not describe any shared risk approach, except for implementing "outlier payments and risk corridors to protect physician practices from financial risk from price increases on drugs or hospital services or patients who need unusually expensive care" under option C (Appendix H). How is risk-bearing contemplated in the bundled payment options?
    - Otherwise, how will the model lower the total overall costs?

4. Please expand on the risk-adjustment approaches to be used in the payment model.
    - Will risk-adjustment be based on headache characteristics using the MIDAS score or also data extracted from claims or electronic health records?
    - Do payment amounts vary by specific ICD-10 diagnosis?
    - How will the proposed risk-adjustment approaches and data needed account for variation between different types of practices such as large hospital center vs. small unaffiliated community practices?
    - How will the model obtain this data from the different practices and use this for risk stratification?

5. The PRT wants to better understand how the risk-based payment options would work in the proposed model. You indicate that because you anticipate that most practices will elect the Basic Bundle in the initial years, your presentation of the advanced payment options are not as fully formed. Yet, they are proposed here.
    - Please tell us what common Part B and Part D headache medications are used for treatment of complex pattern headaches and whether the high cost of some might alter the prescribing patterns of any risk-bearing entities subject to the Option B and C payment.
    - For Options B and C, can you point us to prototypes of how they work operationally and findings of their effectiveness?

6. The Medicare Chronic Care Management (CCM) codes do cover some non-face-to-face services, seemingly for some of the coordination activities proposed in your proposed delivery model. What is the advantage of creating a new payment model rather than adapting existing Medicare CCM codes to support improved management of complex pattern headache patients?
    - What role can these codes play in supporting the delivery model proposed?
    - Are there any potential modifications to these codes or rules governing application of codes in the PFS that could address at least part of the delivery model?

AAN Responses
1/10/2018

Follow-up Items on AAN Proposal from PRT

Questions about the Proposed Patient-Centered Headache Model for Submitter

Epidemiology of Headaches and Treatment

1. **On page 6, you write that the average cost for a patient visit was more than $4000 across all settings (reference #10, MEPS 2014 Consolidated Conditions). Do you literally mean a single patient visit or total spending that a visit/encounter generated, which might include hospitalizations etc.? We will also review the MEPS reference you cite for this fact if you would kindly send it to us, but also please provide detail of what this $4000 represents.**

Our data scientist performed descriptive statistical analysis using data from the 2014 Medical Expenditure Panel Survey Full Year Consolidated Outpatient Visits File. Per the Agency for Healthcare Quality and Research (AHRQ), this file contains characteristics associated with the outpatient visit data, such as the date of the visit, whether or not a doctor was seen, type of care received, type of services provided, expenditures, and sources of payment.[1]

The $4000 represents the average amount Medicare paid for an outpatient visit by any patient with a primary diagnosis of headache or migraine. All patients with expenditures of a 0-value were removed from this calculation to reflect only those that had attributed expenditures. Inpatient visits (i.e., hospitalizations) are not included in this calculation.

We recognize that these data are limited because they may not represent *actual charges* for specific services, but rather *all expenditures* attributed to the headache patients.

The data file defines "expenditures" as follows:

> *2.5.11.1 Expenditures Definition: Expenditures on this file refer to what is paid for health care services. More specifically, expenditures in MEPS are defined as the sum of direct payments for care provided during the year, including out-of-pocket payments and payments by private insurance, Medicaid, Medicare, and other sources. Payments for over-the-counter drugs are not collected in MEPS. Indirect payments not related to specific medical events, such as Medicaid Disproportionate Share and Medicare Direct Medical Education subsidies, are also not included. The definition of expenditures used in MEPS is somewhat different from the 1987 NMES and 1977 NMCES surveys where charges rather than sum of payments were used to measure C-104 MEPS HC-181 expenditures. This change was adopted because charges became a less appropriate proxy for medical expenditures during the 1990s due to the increasingly common practice of discounting charges. Another change from the two prior surveys is that charges associated with uncollected*

[1] https://meps.ahrq.gov/data_stats/more_info_download_data_files.jsp

liability, bad debt, and charitable care (unless provided by a public clinic or hospital) are not counted as expenditures because there are no payments associated with those classifications. While the concept of expenditures in MEPS has been operationalized as payments for health care services, variables reflecting charges for services received are also provided on the file (see below). Analysts should use caution when working with the charge variables because they do not typically represent actual dollars exchanged for services or the resource costs of those services.

2. **We assume that it is not common for complex pattern headaches to first present when people have aged into Medicare. Is that correct?**

The model is targeted at patients with *undiagnosed, difficult to diagnose, or poorly controlled headaches*.

It is quite common for headache disorders to first present in Medicare-eligible populations. In fact, serious etiologies are especially common for the Medicare-eligible. Certain disorders change in phenotype with aging (e.g., migraine), and certain headaches, such as hypnic headaches, medication overuse headache, chronic migraine with cardiovascular disease, or headache with the comorbidities listed in our appendix, commonly first occur in patients over 60 years of age.[2]

We recognize there are a number of other diseases that can present in the Medicare-eligible population that may not be present in younger headache sufferers. For example, arteritis (i.e., inflammatory disease in arteries) often does not first present until after a patient has aged into Medicare.

One of the most common late-onset headache conditions is medication-related headache (note, this is addressed further below). This condition is highly prevalent in Medicare populations who frequently take several medications. Many clinicians do not recognize the symptoms of medication-related headache, particularly if the patient has a genetic predisposition for headache or migraine.

There are several types of headaches that present either later in life or present in an atypical manner. Some of these not previously discussed include:

- Giant cell arteritis
- Aura without migraine
- Parkinson's side-effects
- Headaches in patients with cervical disease.
- Shingles

This is not an exhaustive list.

[2] http://www.turner-white.com/pdf/jcom_aug11_headaches.pdf

Additionally, changes in pattern and quality as well as increase in medical comorbidities may present in Medicare-eligible populations, which may make these headaches more complex or lead to them being unrecognized and undiagnosed.

a. If so, wouldn't your proposal really only address improved management of already diagnosed (accurately or not) migraine/cluster headache patients?

We'd like to maintain our definition of patients with *undiagnosed, difficult to diagnose, or poorly controlled headache* not just those with migraine and/or cluster headache.
This model could certainly be used for Medicare populations as there are several types of headaches that present either later in life or present in an atypical manner (see above).

3. By the time patients enter Medicare, how big a problem is previous misdiagnosis and ongoing mismanagement? In other words, how often would you say a patient who is newly insured by Medicare has been misdiagnosed? And what are some of the wrong diagnoses?

Previous misdiagnosis of headache is extremely common at all ages. However, these headaches become more costly and difficult to treat as patients enter Medicare because of delayed treatment and misdiagnosis. Symptoms in Medicare populations may change or worsen, and certain medications should no longer be used in Medicare populations.

Medication overuse headache is a good example of this. As people get older the number of medications they take significantly increases. One study found that the average number of prescriptions filled increases with age, from 13 for those age 50 to 64, 20 for those age 65 to 79, and 22 for those age 80 and older.[3]

Moreover, many patients take over-the-counter medications such as a combination of ibuprofen/paracetamol/caffeine or acetaminophen alone, which can result in chronic daily headache with medication overuse. In these cases, the medication becomes the reason for the symptoms. To treat, a physician would have to take these patients off all their headache-related medications to treat the underlying headache.

Medication overuse headaches may not be diagnosed at all if the treating physician doesn't know to ask how often the patient is having headaches. Medication overuse headache can often be incorrectly diagnosed as tension type headaches, or as stress-related headaches (not even a real diagnosis). The challenge is that without training in headache medicine, a physician may not recognize the medication overuse headache at all.

Some other misdiagnoses that may occur:

[3] https://hpi.georgetown.edu/agingsociety/pubhtml/rxdrugs/rxdrugs.html

- A substantial number of those with migraine are initially misdiagnosed as sinusitis.[4] There are some patients who may have decades of a "sinus headache" diagnosis and the actual diagnosis is migraine or cluster headache.
- Patients may be diagnosed with "chronic daily headache diagnosis" which is not specific at all.
- Overlooked degenerative changes in the cervical spine and temporomandibular joint (TMJ), which presents as referred pain to the occipital region or auriculo-temporal region. In these cases, the patients may have invasive and expensive procedures done without simple medical management first.
- Arteritis/temporal arteritis is sometimes just diagnosed as headache or tension headaches.

It may also be the case that patients have delayed treatment until aging into Medicare. Some Medicare patients may have previously been uninsured, covered through private plans with high deductibles or co-pays, or covered through Medicaid. The limitations of these plans may have discouraged or limited access to needed care. In other words, it's not just an issue of condition mismanagement; we posit that patients with *undiagnosed, difficult to diagnose, or poorly controlled headaches* may be seeking attention for existing health issues for the first time after gaining access to Medicare.

4. **Based on the literature, what are important variations in treatment approaches for migraine and cluster headaches based on the specialty and experience of the treating physician, for example, the use of oral medications and opioids, Botox, etc.?**

We'd like to maintain our definition of patients with *undiagnosed, difficult to diagnose, or poorly controlled headache* rather than limiting our model to just those with migraine and/or cluster headache.

There are several new options in terms of mode of delivery and novel approaches to headache treatment of which a PCP or APP may not be aware. With regards to migraines: Botulinum toxin is the only FDA approved treatment for chronic migraine. Knowledge of injection paradigm is important to ensure consistency. Infusions of a cocktail of medications may be used at some large centers to break headache cycles.

Other procedures such as nerve blocks and trigger points may not be familiar to some clinicians who don't have expertise in neurologic conditions like headache. There are non-oral routes of delivery available for patients with gastroparesis, or significant decreased oral tolerance during an acute migraine attack.

Additionally, here are newer therapeutic targets on the horizon (e.g., monoclonal antibodies, Calcitonin Gene-Related Peptide (CGRP) antagonists). With cluster headaches, these patients sometimes benefit from repeated nerve blocks or sphenopalatine ganglion block, there is a new portable VNS device that can be used to abort attacks. There are current trials for a SPG implanted stimulator. In addition, a pituitary lesion should be ruled out in any new onset cluster patient. In general, a comprehensive

[4] https://thejournalofheadacheandpain.springeropen.com/articles/10.1186/1129-2377-14-97

approach that includes acute management, prevention, lifestyle/dietary modification and addressing the psychosocial issues keeps the patient out of the ED, while improving the patient's quality of life.

For most headache types the AAN has developed evidence-based guidelines common treatment approaches for both migraine and cluster headache. Two that are particularly relevant are the recent guidelines entitled Botulinum Neurotoxin for the Treatment of Blepharospasm, Cervical Dystonia, Adult Spasticity, and Headache and the 2012 update to the guideline entitled Pharmacologic Treatment for Episodic Migraine Prevention in Adults (note, this guideline is currently being updated by the AAN and will be posted in 2018).

Within each guideline, AAN describes the strength of evidence (i.e., strong, moderate, weak or inclusive) for each class of medication and, when appropriate, makes recommendations for use or disuse, which clinicians can then consult and leverage in clinical decision-making.

The AAN additionally provides a clinical context for each guideline, which provides more details about the recommendations made. For example, for the Pharmacologic Treatment of Migraine Guideline, the AAN writes:

> *Although Level A recommendations can be made for pharmacologic migraine prevention, similar evidence is unavailable to help the practitioner choose one therapy over another. Treatment regimens, therefore, need to be designed case by case. Moreover, decision making must remain with the physician and the patient to determine the optimal therapy. Often trial and error is needed.*

Also, the AAN provides a short summary of the guideline for physicians as well as patients to facilitate communication of decisions and empower clinicians to choose the appropriate treatment for their patient.

A neurologist or headache specialist would be more readily able to use "Level B evidence" as the initial choice on an individual case base assessment. For example, there is Level A evidence for Depakote/valproate, however this would not be the first choice in a woman of childbearing age.

Due to these nuances and complications in treatment it is difficult for a provider not versed in headache management to stay on top of emerging guidelines adequately. That is why this population (undiagnosed, difficult to diagnose and poorly controlled) requires specialty focus.

a. **Is evidence of different treatment approaches by different types of clinicians important in setting out the objectives of the delivery model you propose? In other words, where there may be opportunities for improving care and reducing use of low-value services.**

Yes. For example, PCPs may be more likely to use neuroimaging for chronic pain headache than neurologists and other specialists.[5] Imaging contributes to substantial health care costs in the US ($1 billion in annual costs and growing) despite guidelines, such as those noted above, and other campaigns, such as *Choosing Wisely*, which discourage routine use.[6]

PCPs may be more likely to use neuroimaging and/or may not order the appropriate imaging studies. For example, PCPs will often order a CT scan for headaches. The output from these scans do not include the base of the patient's skull, subcortical white matter lesions, and other abnormalities which are not as apparent on CT.

An MRI is preferable for most headache patients **who do require imaging**. So, when patients with undiagnosed, difficult to diagnose, or poorly controlled headaches are referred to a neurologist, a patient who needs imaging will often need an MRI (after already having been administered a CT scan). This ultimately drives up the cost of care.

Of course, most patients do not need an MRI. This model will support patients having the appropriate test completed for their clinical symptoms.

PCPs and ED physicians are more likely to prescribe butalbital containing compounds which may lead to medication overuse.[7]

Significant costs are attributed to ED use and may be curtailed by outpatient management including infusion services, or comprehensive acute and rescue regimen and back-up regimen mutually determined by the physician and patient.

In addition, primary care may not feel comfortable with preventive medications beyond Topamax/topiramate or a low dose beta-blocker. Appropriate preventive medications greatly decrease inpatient and outpatient resource utilization.

Care Delivery Model

1. **Although most of the proposal seems to be a model for caring for complex pattern headache patients, often on referral, at times it seems to be a more general headache delivery model, such as when the proposal refers to an established "Headache Care Team" and also when it presents a Triage Protocol "to determine which patients need highly specialized headache care," i.e., those with acute, disabling headaches.**
    a. **Please clarify. What patient population – those with headaches or only those with complex pattern headaches would be recipients of the new delivery model?**

[5] https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1835347
[6] http://www.choosingwisely.org/about-us/
[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4079825/; https://www.ncbi.nlm.nih.gov/pubmed/12390637

Acute and disabling headache may be part of the model, but our APM is designed for *undiagnosed, difficult to diagnose, or poorly controlled headache* rather than limiting our model to just those headache types listed above.

As listed in Appendix B, current ICD-10 codes cover the type of headaches that may be included in the model.

Patients *whose complex headache symptoms have been managed* would be moved into Category 3 wherein they may continue to regular in-person or virtual care by other members of the HCT (i.e., a PCP). However, the neurologist or headache specialist would continue to monitor patient data and consult with the other members of the HCT. The triage protocol would support determination of whether a patient is ready to be moved into Category 3.

b. You write on p.2, "This model proposes three distinct categories of care based on stage and complexity of headaches." The proposal indicates the Headache Care Team "includes a neurologist, headache care specialists, primary care physician, a patient care coordinator, nutritionist, physical therapist and/or mental health or social service provider to support patient care". On p4, the proposal states that "low complexity patients would… remain with the primary care physician" for ongoing management under Category 3, with coordination between the PCP and neurologist, however on p10, it states ongoing management in category 3 could be supported by an APP within a neurology practice, rather than a PCP. We do not follow.

i. Please make clear the relevance of the three categories with regard to the provision of care.

Thank you for pointing out the variations of the model. These represent options available to participants based on 1) the needs of the patient 2) the practice setting and 3) the geography. For example, a rural setting may not have access to a headache specialist, but may have many APPs available to manage care. Please see Table 1 for illustrative examples of how the teams may be implemented in different care settings.

To clarify, the HCT is based on patient need and would likely not always include every member listed. In **Categories 1 & 2**: The neurologist or headache specialist leads the delivery and management of care. In **Category 3:** The PCP leads delivery of care with ongoing data monitoring from the neurologist or headache specialist. **Across all three categories** the neurologist or headache specialist is involved in the delivery of care and leads care planning. Similarly, an APP may support care at all three stages of care delivery as part of a neurology or primary care practice.

c. Please explain the function of the various team members, including the physical therapist, nutritionist, mental health therapist or social worker, specifically in reference to treatment for the ICD-10 conditions listed in Appendix B. These disciplines would seem

relevant for a broader headache team, but how are they relevant specifically for complex pattern headaches.

We refer the PRT to the language throughout our proposal where we indicate the model includes patients with *undiagnosed, difficult to diagnose, or poorly controlled headache.*

i. **What is the role of the care coordinator (Appendix A)?**
The coordinator is frequently not a treating provider. This role supports the treating clinician by coordinating care across the HCT. For example, a patient may need to see a nutritionist as part of their headache care plan. The care coordinator would facilitate the referral to the nutritionist, obtain and disseminate information collected by the nutritionist across the different treating clinicians, and otherwise support non-clinical needs.

There is evidence that nurse care coordinators have more significant impact on quality and cost[8] but the role may be filled by an MA or other office staff per available practice resources.

ii. **How does that role differ from that of the Advanced Practice Provider (described in the proposal on p10 as "non-physician members of the care team, including NPs, PA, certified nurse midwives, clinical psychologists, nonclinical psychologists, clinical nurse specialists")?**

The APP is expected to be a treating clinician.

We designed this model to be implemented flexibly based on the resources available to the participating practice. In some smaller practices, the APP may function as the care coordinator. In larger practices, there may be a separate coordinator who oversees the communication between providers/scheduling/etc.

iii. **What are the skills and qualifications of the care coordinator?**

In general, skills and qualifications may be someone who is well-organized, has good interpersonal skills, has the ability to work in a medical environment, and facilitate communication across disparate settings. Clinical expertise is not required, but it may be helpful to carry out the responsibilities of the care coordinator.

iv. **Who does the patient primarily interact with?**
It depends on patient need and diagnosis. This is a patient-centered model. We envision that a neurology or headache specialist practice would lead care in Categories 1 & 2. However, if an APP works and delivers care in these practices the patient may see the APP.

An identified care coordinator would help the patient navigate their care as a single point of contact. This person could be in the specialist's office or the PCP office.

[8] https://www.ncbi.nlm.nih.gov/pubmed/28974106

d. The proposal seems to be describing an actual team with a primary care physician included, although at time references virtual teams (p7) across practices.

This model is not limited to teams physically located in one setting, though this may certainly be an approach used by participants. The model may be implemented via a medical home "neighborhood" approach in which patient care is coordinated across a wide array of providers and settings, supporting PCMH and ACOs alike.[9] In instances of the APM where physicians are not co-located or part of the same system, the team will likely be virtual in nature. In these settings, novel technology approaches may be used to coordinate care, for example: video telemedicine connecting the patient, the PCP and the specialist.

Please see Table 1 for illustrative examples of how the teams may be implemented in different care settings.

i. Given that patients with complex pattern headaches presumably present with symptoms across most ambulatory care sites – office practices, emergency rooms, urgent care centers – and see a myriad of primary care practitioners – in the hundreds of thousands -- how can primary care physicians participate on a real team and gain "preferred provider status" as described on p7?

As noted throughout our responses and the proposal, our APM is designed for patients with *undiagnosed, difficult to diagnose, or poorly controlled headache*. We do not recognize the term complex pattern headache.

In order to participate in this APM there would have to be an agreement between the PCP and specialist leading care, which would then grant the PCP "preferred provider status". The contract would articulate each physician's responsibility including two-way communication between all three parties and coordination of care.

Preferred provider status and referral networks are well-documented strategies for reducing costs and improving quality. For example, there is evidence that patients in preferred provider organizations (PPOs) who receive care exclusively from PPO providers receive recommended care.[10]

Finally, patients who opt-in to the model agree to receive all headache-related care from their HCT as a condition of participation. This would effectively restrict the number of PCPs a patient could see, thus enabling participating PCPs to truly participate on a real team and gain "preferred provider status."

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[9] https://pcmh.ahrq.gov/sites/default/files/attachments/Coordinating%20Care%20in%20the%20Medical%20Neighborhood.pdf

[10] http://onlinelibrary.wiley.com/doi/10.1111/j.1475-6773.2007.00725.x/full

e. Is the model described really a team based within a neurology practice which sees patients on referral from primary care physicians and then provides guidance back to the primary care physician once patients achieve maintenance status?

No, though this can certainly be one approach to the model. Please see Table 1 for illustrative examples of how the teams may be implemented in different care settings.

f. What are the qualifications of the "headache specialist" you refer to?

Neurologists have expertise in treatment and care of headache patients based on their training. Additional or advanced expertise may be obtained via fellowships and completion of certifications in headache medicine (e.g., via United Council for Neurologic Subspecialties). There are also neurologists, internists, psychiatrists and other physicians with expertise in headache based on additional training, fellowship, and/or specific experience in headache medicine.

This model encourages headache medicine specialists to see the most complicated cases. Note that we do not want to suggest that a headache specialist is required for all *undiagnosed, difficult to diagnose, or poorly controlled headache*s. In fact, because the majority of headache medicine specialists are located in urban centers, patients in rural communities may not always have access to this level of specialist.

i. **How is that different or equivalent to a neurologist?**
Headache specialists receive additional training in headache medicine via fellowship, training and specific experience in headache medicine.

ii. **Does the submitter have any evidence/data to show what should be the minimum standards for designation of a headache specialist?**
(See above and below).

g. Are there some prototype models - for either general headache teams or complex pattern headache teams that seem to be the focus of this proposal – being piloted in integrated health systems, such as Kaiser Permanente or large neurology centers?

i. **What can we learn from their experiences?**

There are headache medicine centers that are implementing similar models (e.g., Baylor, DENT). Some of these are participating in Comprehensive Primary Care Plus (CPC+), for example, where they have implemented many of the care delivery elements we have proposed. However, they are not being measured based on performance on headache-specific quality and outcome measures that are used by neurologists and headache medicine physicians.

Large headache centers, and some larger headache and neurology centers do use a comprehensive treatment model aimed at keeping the patient out of the ED. DENT Neurologic institute is one example. Their open access model allows patients to be seen within a short period of time. This saves ED-related costs, costs attributed to misdiagnosis or inappropriate treatment.

We are additionally aware of several small practices that have instituted programs that are consistent with the model we proposed. These practices have staff that function as care coordinators and frequently leverage innovative technology to support the delivery of headache care. Those that participated in preparing the APM leveraged the experiences of these practices in developing the APM submitted to PTAC for consideration.

h. The Medicare Physician Fee Schedule already pays for a "Welcome to Medicare" initial preventive visit which beneficiaries can take advantage of within the first 12 months of Part B eligibility and as part of "annual wellness visits" with their regular physician.

i. Why wouldn't this serve as adequate triage to assure referral of patients who would benefit from a consultation with a headache specialist for complex pattern headaches?

As noted throughout our responses, our APM is designed for patients with *undiagnosed, difficult to diagnose, or poorly controlled headache*. We do not recognize the term complex pattern headache.

If done properly this preventive visit could serve as the entry point to the APM. And, as part of the HCT, PCPs would be encouraged to add headache screeners to this visit. Indeed, if practitioners dedicate the time allotted with their patients they may be able to effectively recognize that neurologist or specialist care is needed to correctly diagnose and/or control a patient's headache. However, as noted above, misdiagnosis is very common despite the availability of the "Welcome to Medicare" initial preventive visit and "annual wellness visits." Additionally, this triage does not replace the services described in our care delivery model.

ii. While there is appeal of the model in a younger population, as suggested by our initial questions, it is not clear that this particular delivery model is particularly needed in the Medicare patient population. Please explain.

It is not uncommon for Medicare beneficiaries to present with *undiagnosed, difficult to diagnose, or poorly controlled headache*. Furthermore, as we included in our proposal, 2014 MEPS data shows that there were nearly 3.5 million patient visits for headache among those patients eligible for and enrolled in Medicare. This suggests an ample Medicare population that could participate in this model if implemented.

i. Please describe what is gained from the 20-30 minute "pre-assessment" by the medical assistant or registered nurse (p4) prior to seeing the neurologist for another 30-60 minutes. The sample headache diary template (Appendix E) appears to be weekly information filled out by the patient, not staff.

i. What information does this yield about the patient that improves the quality and efficiency of the process?

ii. Can the submitter provide pre-assessment protocols or other materials for the PRT to review?

By empowering nursing staff or medical assistants to conduct a pre-assessment before seeing the neurologist or headache specialist, this model will allow the treating physician to practice to the "top of their license," leveraging the full extent of their education and training, rather than collecting data that may be easily obtained and recorded by other office staff. The range of time given for the pre-assessment is illustrative and may be greater or less than the 20-30 minutes allotted. We have attached a sample pre-assessment protocol that *may* be used for the model.

It is during the **post-visit** that the headache diaries are introduced. The post-visit would not be for administering the diary, but rather educating the patient on how to use such a diary. Note the template included in our proposal is meant to be a sample; there are a number of other headache diary templates, many of which are daily in nature. The post-visit time would serve to provide additional education around care plan adherence, for example.

j. How would this proposed delivery model work in different types of settings - such as rural independent practice vs. a fully integrated delivery system or large urban neurology practice? Please be as specific as possible for each type of setting.

Please see Table 1 for illustrative examples of how the teams may be implemented in different care settings. We intentionally designed the model to be flexibly implemented per the realities of each setting.

k. There is interest from PRT members to review the Axon registry and its measures. Please provide additional detail with a complete set of measures.

Here is a link to several videos demonstrating the Axon Registry. Included in the series are videos of the quality improvement dashboard and its functionality as well as a technical overview.

Note that we are currently revamping the portal and dashboard for 2018, so the portal may look and feel differently and will have improved functionality after the updates are implemented.

If you would like a live demonstration, please let us know and we can schedule a conference call with our Registry Program Manager.

Follow-up Items on AAN Proposal from PRT

Payment Methodology

1. **The PRT would like to understand what type of patient specifically is the target of this model. Please provide all the criteria for the patient to be eligible and included in the model.**

The target of our APM is patients with undiagnosed, difficult to diagnose and/or poorly controlled headaches. The criteria are those listed in Appendix B.

a. **Does the patient require a referral from a primary care or ER physician to be included in the model? Is that the trigger for the "predetermined, fixed payment per patient?"**

No, but we do encourage referrals. No, the trigger is the claim listing the ICD-10 and the patient opting into the model.

b. **The model submitters note that patients have the choice of opting into the program. The PRT assumes that a formal opt-in is needed to trigger the add-on payments in the model.**
   i. **Is that correct?**

Yes. We note the following in our proposal:

> *All patients must opt-in to the proposed care plan and model in order for physicians to receive the PCHCP. Patients must agree to adhere to the care plan, to receive all headache-related care from the neurologist or headache specialist, and opt-in to the model; those who do enter Category 1 of the model.*

   ii. **Does the beneficiary give up any freedom of choice of provider at any time during the period when they have opted in?**

Yes, the beneficiary agrees to receive all headache-related care from members of the HCT.

   iii. **How are payments affected if opt-in patients are actively obtaining care outside of the headache team?**

Non-headache related care would be paid for via the regular Physician Fee Schedule (PFS). The patients agree when opting into the program to receive all headache-related care from members of the Headache Care Team (HCT). Those that do not will be excluded from the model.

   iv. **What are the advantages and disadvantages of patients opting in?**

The advantage is that patients will be actively engaged in their care and guaranteed choice in their care plan. The process of opting in also affords the opportunity to explain the members and roles of the health care team, how to use them and how to communicate with them, including telemedicine options. Conversely, some patients who would be good candidates for the model will not elect to participate. However, as this is a patient-centered model, we believe the advantages outweigh the disadvantages.

2. **The PRT wants to better understand how the model will likely motivate clinicians to generate cost savings. The proposed monthly payments are larger than current E&M payments.**

We were clear that the proposed monthly payments included in the appendix of the proposal were illustrative; we intentionally did not propose a monthly payment as we would like to work with payers to determine an appropriate amount.

We have developed a financial model to estimate the financial impact to each of the key stakeholders: payers, practices, and health systems. The overall goal of the model is to use medical expense savings from reductions in hospitalizations, ED visits, medication and imaging to lower the total cost of care and increase physician payments.

We would appreciate the opportunity to demonstrate this financial model on a call with our Preliminary Review Team.

According to our model:

- The payer/CMS would be guaranteed a minimum 5% reduction in Part B costs. The total amount of savings increases as physicians are successful at identifying savings.
- Physician and payer incentives are aligned. Management and Monitoring Costs increase in proportion to overall savings, adding to their margin.
- As physicians take on greater risk around savings for hospitalizations, ED visits, medication use and imaging (i.e., Options C & D) and they accrue more in Management and Monitoring Costs, and hence total revenue.

    a. **Will there be cost savings to make up the difference?**

Yes, we anticipate cost savings. See the previous answer.

    b. **Alternatively, practices that become designated headache centers could take upside and downside risk based on spending performance, but you do not describe any shared risk approach, except for implementing "outlier payments and risk corridors to protect physician practices from financial risk from price increases on drugs or hospital services or patients who need unusually expensive care" under option C (Appendix H). How is risk-bearing contemplated in the bundled payment options?**

As practices gain experience and comfort with the APM, we anticipate that they will be more receptive and prepared to enter into risk-based options. Down the line, as the model evolves, the AAN is prepared to work with payers to develop the risk-bearing approach. Similarly, the AAN is prepared to work with participating physicians to educate them on the potential benefits of increased risks.

However, it is imperative that the risk be gradually introduced so as to be appealing to practices of all sizes and geographic settings.

In our APM, physicians take on risk by accepting a capped budget for the care of the aforementioned headache population. Within that budget, physicians are obligated to incur the expense of supporting team-based care.

Savings to the payer is guaranteed, but unless the physician efficiently manages diagnosis and care, their expenses may outweigh the additional revenue from the Management and Monitoring Costs. Thus, downside risk to the physician is not capped. As physicians gain experience with the model, the percentage of payer savings devoted to the Management and Monitoring Costs can be adjusted to balance payer and physician incentives.

Within the model and budget, patient complexity and co-morbidities are addressed using patient categories and levels of coding. This will allow appropriate payment for exceptional patients.

c. Otherwise, how will the model lower the total overall costs?

As we indicated in our proposal, we anticipate that broad implementation of the model would yield cost savings for payers and society by paying neurologists and headache specialists up-front for more time with complex patients, which would result in care delivery innovations, accurate and timely diagnosis, proper use of preventive treatments, reduced use of opioids and other inappropriate prescription medications, and reduced unnecessary emergency department and urgent care use.

As indicated above, we have developed a dynamic model that represents the financial impact of the model and shows a lower total overall cost due to reduced *inappropriate* imaging, ED use, and hospitalizations. We would be happy to schedule a time to review this model with our Preliminary Review Team.

Mechanisms that lower total cost include reductions in:

- Part B budget (capped at 95% of current Medicare expenditures)
- Hospitalizations
- ED visits
- Medication costs
- Imaging costs
- Efficiencies in care delivery

The overall mechanism of our APM is to find efficiencies in these categories, lower total cost and divert a portion of the savings to physicians in the form of Management and Monitoring Costs.

3. **Please expand on the risk-adjustment approaches to be used in the payment model.**
    a. **Will risk-adjustment be based on headache characteristics using the MIDAS score or also data extracted from claims or electronic health records?**

Risk adjustment is based on specific patient characteristics such as frequency, headache severity, select comorbidities, patient demographic information, and resource use. All this data may be contained in an EHR or claim.

Much of this data can be incorporated into the Axon Registry. For example, the MIDAS score methodology is currently contained within Axon. The Axon Registry is a key mechanism to provide group, physician, and national-level comparisons to see how effective physicians are at improving MIDAS scores and quality performance more broadly.

    b. **Do payment amounts vary by specific ICD-10 diagnosis?**

Within Category 2 Levels 4 & 5, ICD-10 codes are among criteria used to identify the comorbidities used to vary payment amounts. However, other levels use one or more of the risk-adjustment criterion listed above.

AAN will produce resources to support correct coding under the model. Part of the responsibility of the care coordinator role may also be to support the physician in coding. For that reason, in the first year of the APM, we suggest uncoupling payment from risk adjustment; it takes away the incentive to code inappropriately.

    c. **How will the proposed risk-adjustment approaches and data needed account for variation between different types of practices such as large hospital center vs. small unaffiliated community practices?**

This model was designed for difficult to control patients, and thus is more likely to be used in a referral or large hospital center, however, we designed the model to serve a multitude of practice types and settings. Moreover, key assumptions in the financial model, such as the percentage of payer savings devoted to management/monitoring and the payer budgeted savings, could be adjusted for smaller practices who have smaller populations. As we gain more experience with the headache APM, other possible solutions will emerge.

    d. **How will the model obtain this data from the different practices and use this for risk stratification?**

We anticipate Axon Registry will be a key data source. We would also need payer data such as claims to support risk stratification.

4. **The PRT wants to better understand how the risk-based payment options would work in the proposed model. You indicate that because you anticipate that most practices will elect the Basic Bundle in the initial years, your presentation of the advanced payment options are not as fully formed. Yet, they are proposed here.**
    a. **Please tell us what common Part B and Part D headache medications are used for treatment of complex pattern headaches and whether the high cost of some might alter the prescribing patterns of any risk-bearing entities subject to the Option B and C payment.**

We have modeled this in our financial model, and specifically included the impact of opioids and CGRPs. The latter are predicted to cost up to $10,000 per patient per year, and will need to be carefully managed.

    b. **For Options B and C, can you point us to prototypes of how they work operationally and findings of their effectiveness?**

This model has not been implemented in the US to-date. As previously noted, many forward-thinking Headache Centers and neurology practices have implemented elements of the care delivery model (e.g., DENT Neurologic Institute, Baylor), but these are not reimbursed via the payment methodology we outline in our proposal.

In Germany, there is evidence that headache-specific bundles may be effective at improving quality and reducing costs.[1]

The West German Headache Centre worked with payers to develop a system of integrated care in which key specialties are co-located and referral networks are established for neurologists in private practice. As in the PCHCP, services are tailored to the patient's needs.

Research shows that payers save between €1500 and €2000 per patient per year compared to standard care because of fewer imaging/test duplications, fewer hospitalizations, and fewer ED visits.[2] The approach is also linked to improve health outcomes.[3]

    c. **The Medicare Chronic Care Management (CCM) codes do cover some non-face-to-face services, seemingly for some of the coordination activities proposed in your proposed delivery model. What is the advantage of creating a new payment model rather than adapting existing**

[1] https://www.advisory.com/International/Research/Global-Forum-for-Health-Care-Innovators/Expert-Insight/2015/the-case-for-specialists-in-integrated-care
[2] https://bmcneurol.biomedcentral.com/articles/10.1186/1471-2377-11-124
[3] https://link.springer.com/article/10.1007/s10194-011-0348-y

Medicare CCM codes to support improved management of complex pattern headache patients?

i. **What role can these codes play in supporting the delivery model proposed?**
ii. **Are there any potential modifications to these codes or rules governing application of codes in the PFS that could address at least part of the delivery model?**

CMS might argue that a neurologist should use CCM codes, but current policy only allows the physician who is managing **all aspects of the patient's care** to bill for CCM. Since only one physician can use this code per patient at a time, and because headache patients on Medicare often have multiple comorbidities, it is likely that the PCP overseeing patient care would use this code.

Additionally, the criteria for use of the CCM are complicated to meet, require burdensome documentation, and, importantly, take us back to a FFS structure.

Moreover, while PCHCP would support care coordination activities, it would also allow for other innovations in care delivery such as ongoing patient monitoring via telehealth, which is not currently supported by the CCM code.

We do budget for the Management and Monitoring Costs in our financial model, but these costs are derived from savings, which, does not negatively impact overall costs.

Table 1: Model by Setting

Setting	Available Personnel[1]	Supportive Infrastructure[1]	Illustrative Example
Independent rural neurology practice	Neurologist, medical assistant	EHR[2,] videoconferencing software	Given limited personnel within the practice, the participating practice partners with local providers (e.g., PCPs, nutritionist, physical therapist and/or mental health **or** social service provider to support patient care) based on patient needs. Using videoconferencing technology, the neurologist treats patients remotely and supports the delivery of HA care at the PCP, when required. The APM is "virtual" in that members are not co-located, and share patient information using Health IT.
Independent or small urban neurology practice	Neurologist, nursing staff, medical assistant, practice administrator	EHR[2]	Given limited personnel within the practice, the participating practice partners with local providers (e.g., PCPs, nutritionist, physical therapist and/or mental health **or** social service provider to support patient care) based on patient needs. The APM is "virtual" in that members are not co-located, and share patient information using Health IT.
Fully integrated health system	Neurologist(s), non-neurologist physicians, APP(s), nursing staff, medical assistant(s), practice administrator	Interoperable EHR, videoconferencing software	The participating practice has all needed personnel and infrastructure within the health system. The participating neurologist would identify HCT providers within the system based on patient needs. When appropriate, APPs would manage care of diagnosed patients in Categories 2 & 3, and the practice would make use of videoconferencing technology to monitor patients remotely. In this instance, the HCT represents an actual team within a system.
Large urban neurology practice or headache medicine center	Neurologist(s), APP(s), nursing staff, medical assistant(s), practice administrator	Interoperable EHR, videoconferencing software	As the practice would not have access to non-neurologist physicians, the participating practice partners with local providers (e.g., PCPs, nutritionist, physical therapist and/or mental health **or** social service provider to support patient care) based on patient needs. When appropriate, APPs would manage care of diagnosed patients in Categories 2 & 3, and the practice would make use of videoconferencing technology to monitor patients remotely. The APM is "virtual" in that members are not co-located, and share patient information using Health IT.

[1] The personnel and infrastructure listed are *commonly* but not always available in the settings listed.

[2] EMR may not be interoperable or ONC Certified.

Table A.1 Distribution of Medicare Visits where Headache is Primary Diagnosis by Practitioner, all patients*
Table A.2 Distribution of Medicare Visits where Headache is Primary Diagnosis by Practitioner, Patients Aged 64 years or younger
Table A.3 Distribution of Medicare Visits where Headache is Primary Diagnosis by Practitioner, patients aged 65 years or older

				Carrier Lines		Facility Revenue Centers / Claims		
Headache Type	ICD_DGNS_CD1 values	ICD descriptor	Total Visits (N)	Primary Care—provider**	Neurology--provider	Inpatient discharges	Outpatient claims with ED revenue center 0450-0459	All other outpatient claims
Prvdr_spclty codes				(See note)	13 - Neurology	---	---	---
All headache disorders								
Migraines	G43001	Migraine without aura, not intractable, with status migrainosus						
	G43009	Migraine without aura, not intractable, without status migrainosus						
	G43011	Migraine without aura, intractable, with status migrainosus						
	G43019	Migraine without aura, intractable, without status migrainosus						
	G43101	Migraine with aura, not intractable, with status migrainosus						
	G43109	Migraine with aura, not intractable, without status migrainosus						
	G43111	Migraine with aura, intractable, with status migrainosus						
	G43119	Migraine with aura, intractable, without status migrainosus						
	G43401	Hemiplegic migraine, not intractable, with status migrainosus						
	G43409	Hemiplegic migraine, not intractable, without status migrainosus						
	G43411	Hemiplegic migraine, intractable, with status migrainosus						
	G43419	Hemiplegic migraine, intractable, without status migrainosus						
	G43501	Persistent migraine aura without cerebral infarction, not intractable, with status migrainosus						
	G43509	Persistent migraine aura without cerebral infarction, not intractable, without status migrainosus						
	G43511	Persistent migraine aura without cerebral infarction, intractable, with status migrainosus						
	G43519	Persistent migraine aura without cerebral infarction, intractable, without status migrainosus						
	G43601	Persistent migraine aura with cerebral infarction, not intractable, with status migrainosus						
	G43609	Persistent migraine aura with cerebral infarction, not intractable, without status migrainosus						
	G43611	Persistent migraine aura with cerebral infarction, intractable, with status migrainosus						
	G43619	Persistent migraine aura with cerebral infarction, intractable, without status migrainosus						
	G43701	Chronic migraine without aura, not intractable, with status migrainosus						
	G43709	Chronic migraine without aura, not intractable, without status migrainosus						
	G43711	Chronic migraine without aura, intractable, with status migrainosus						
	G43719	Chronic migraine without aura, intractable, without status migrainosus						
	G43A0	Cyclical vomiting, not intractable						
	G43A1	Cyclical vomiting, intractable						
	G43B0	Ophthalmoplegic migraine, not intractable						
	G43B1	Ophthalmoplegic migraine, intractable						
	G43C0	Periodic headache syndromes in child or adult, not intractable						
	G43C1	Periodic headache syndromes in child or adult, intractable						
	G43D0	Abdominal migraine, not intractable						
	G43D1	Abdominal migraine, intractable						
	G43801	Other migraine, not intractable, with status migrainosus iii						
	G43809	Other migraine, not intractable, without status migrainosus						
	G43811	Other migraine, intractable, with status migrainosus						
	G43819	Other migraine, intractable, without status migrainosus						
	G43821	Menstrual migraine, not intractable, with status migrainosus						
	G43829	Menstrual migraine, not intractable, without status migrainosus						
	G43831	Menstrual migraine, intractable, with status migrainosus						
	G43839	Menstrual migraine, intractable, without status migrainosus						
	G43901	Migraine, unspecified, not intractable, with status migrainosus						
	G43909	Migraine, unspecified, not intractable, without status migrainosus						
	G43911	Migraine, unspecified, intractable, with status migrainosus						
	G43919	Migraine, unspecified, intractable, without status migrainosus						
Cluster headaches	G440	Cluster headaches and other trigeminal autonomic cephalgias (TAC)						
	G4400	Cluster headache syndrome, unspecified						
	G44001	…… intractable						
	G44009	…… not intractable						
	G4401	Episodic cluster headache						
	G44011	…… intractable						
	G44019	…… not intractable						
	G4402	Chronic cluster headache						
	G44021	…… intractable						
	G44029	…… not intractable						
	G4403	Episodic paroxysmal hemicrania						
	G44031	…… intractable						
	G44039	…… not intractable						
	G4404	Chronic paroxysmal hemicrania						
	G44041	…… intractable						
	G44049	…… not intractable						
	G4405	Short lasting unilateral neuralgiform headache with conjunctival injection and tearing (SUNCT)						
	G44051	…… intractable						
	G44059	…… not intractable						
	G4409	Other trigeminal autonomic cephalgias (TAC)						
	G44091	…… intractable						

	G44099	…… not intractable
Other headache syndromes		
	G441	Vascular headache, not elsewhere classified
	G442	Tension-type headache
	G4420	Tension-type headache, unspecified
	G44201	…… intractable
	G44209	…… not intractable
	G4421	Episodic tension-type headache
	G44211	…… intractable
	G44219	…… not intractable
	G4422	Chronic tension-type headache
	G44221	…… intractable
	G44229	…… not intractable
	G443	Post-traumatic headache
	G4430	Post-traumatic headache, unspecified
	G44301	…… intractable
	G44309	…… not intractable
	G4431	Acute post-traumatic headache
	G44311	…… intractable
	G44319	…… not intractable
	G4432	Chronic post-traumatic headache
	G44321	…… intractable
	G44329	…… not intractable
	G444	Drug-induced headache, not elsewhere classified
	G4440	…… not intractable
	G4441	…… intractable
	G445	Complicated headache syndromes
	G4451	Hemicrania continua
	G4452	New daily persistent headache (NDPH)
	G4453	Primary thunderclap headache
	G4459	Other complicated headache syndrome
	G448	Other specified headache syndromes
	G4481	Hypnic headache
	G4482	Headache associated with sexual activity
	G4483	Primary cough headache
	G4484	Primary exertional headache
	G4485	Primary stabbing headache
	G4489	Other headache syndrome
Headache NOS	R51	Headache

* Beneficiaries enrolled in Medicare A&B, with no Medicare Advantage enrollment

** We had a lot of trouble earlier identifying primary care physicians. For the AAFP PRT, we iterated a lot, and came up with three alternatives:

Definition 1: Family Practitioners for whom Ambulatory Care E&M Services Account for 60% or more of Allowed Charges
prvdr_spclty = 08

Definition 2: Family Practitioners, General Practitioners and Internal Medicine Specialists for whom Ambulatory E&M Services Account for 60% or more of Allowed
prvdr_spclty in (01, 08, 11)

Definition 3: Family and General Practitioners, Internal Medicine Specialists, Pediatricians and Geriatricians for whom ambulatory, nursing-home, and home E&M care
prvdr_spclty in (01, 08, 11, 37, 38)

Cleveland Clinic Canada

Headache Intake Questionnaire

Toronto Health and Wellness Centre
Brookfield Place, Suite 3000
181 Bay Street, PO Box 818
Toronto, Ontario M5J 2T3
Tel: (416) 507-6600 Fax: (416) 507-6630

Cleveland Clinic Canada

Toronto Health and Wellness Centre
Brookfield Place, Suite 3000
181 Bay St., PO Box 818
Toronto, ON M5J 2T3
Tel: 416-507-6600 Fax: 416-507-6610

Headache Education & Prevention Program Questionnaire

Personal Information				
Last Name	Given Name(s)			
Home Address				
City	Prov./State	Postal Code	Primary Phone #	Secondary Phone #
Email	Preferred Contact Method			
Emergency Contact	Relationship	Emergency Contact Number:		
Where were you born?	Marital Status			Age of children (if applicable)
☐ Canada ☐ Other	☐ Single ☐ Married ☐ Common Law ☐ Divorced ☐ Widowed ☐ Separated ☐ Long term relationship ☐ Other			

Physicians and Allied Health Professionals			
Name	**Specialty**	**Phone**	**Fax**

Current Health Problems (Attach relevant documents and test results if applicable.)	**Date of Onset**

Past Medical History (Attach relevant documents and test results if applicable.)	**Date**

Past Surgical History and Injuries (Attach medical documents and test results.)	**Date**

Medications and Supplements (List all prescription and supplements)

Name	**Dosage**	**Frequency**	**Date Started**

Do you have any medication allergies? Please list.

Family History

Mother	Father
☐ Alive Age ..... ☐ Deceased Cause of death	☐ Alive Age ..... ☐ Deceased Cause of death .....
Health Concerns	Health Concerns .....

Siblings

# of Brothers ..... **Sisters** ..... **Health Concerns** .....

Does anybody in your family have a history of… (List details – who, what age, specific condition, etc.)

Heart Disease (heart attack, stroke, heart failure, high blood pressure, etc.) .....

Neurologic Disease (seizures, brain tumors, epilepsy, etc.) .....

Migraines or other headaches? .....

Work History

Highest level of education			Current occupation	Currently working?
				☐ Yes ☐ On disability ☐ No ☐ Retired
Self employed?	Hours per day?	Hours per week?	Length of time at current employer	Stress level
☐ Yes ☐ No				☐ Low ☐ Medium ☐ High ☐ Extreme

LIFESTYLE HEALTH BEHAVIOURS

How would you rate your health in general? Excellent □ Good □ Average □ Poor □

Sleep Questions:	How many hours of sleep do you get each night? _____ Do you have problems falling asleep **Yes** □ Problems staying asleep **Yes** □ **No** □
Eating Behaviours:	Do you eat breakfast each morning? **Yes** □ **No** □ Do you eat lunch each day? **Yes** □ **No** □

On average, how much caffeine do you consume daily? (*please note the number of drinks/day)*	**Coffee _____**	**Tea _____**	**Soft Drinks/cola/pop Coke)_____**
Are you a current smoker?	**No** □ **Yes** □ If yes, how much do you smoke?	**Are you an ex-smoker?**	**No** □ **Yes** □ If yes, when did you quit?
Do you use any illicit drugs?	**No** □ **Yes** □ If yes, which one(s) _____ _____ _____ _____	**Have you ever had problems with illicit drugs?**	**No** □ **Yes** □ If yes, which one(s) _____ _____ _____ _____
How much alcohol do you drink on average?	drinks per day □ ___ per week □ ___ per month □ ___	**Have you ever had a problem with alcohol?**	**No** □ **Yes** □

Stress level at work:	Mild □	Moderate □	High □ Very High □
Do you manage stress well?	Yes □	No □	Describe _____
How do you manage stress? (check all that apply)	Exercise □		Describe _____
	Relaxation techniques □		Describe _____
	Hobbies □		Describe _____
	Prayer/Spiritual activities □		Describe _____
	Family Relationships □		Describe _____
	Social Relationships □		Describe _____

HEADACHE-SPECIFIC HISTORY

****** For each question, check all the boxes that apply to you (ie you may check more than 1 box)***

ONSET

1. Did you suffer from headaches when you were younger?
   - ☐ As a child
   - ☐ As a teenager
   - ☐ In my 20's – 40's
   - ☐ In my 50's or 60's

   When were your headaches at their worst? _____

2. When did your current headache problem begin?
   Headaches became a problem _____ Months ☐ Years ☐ ago.

3. Precipitating Event - *Was there a precipitating event or trigger for your current headache problem?*
   - ☐ None known
   - ☐ Specific stress _____
   - ☐ Injury _____
   - ☐ Motor vehicle accident _____
   - ☐ Illness _____
   - ☐ Menarche (first period)
   - ☐ Pregnancy
   - ☐ Birth Control Pill
   - ☐ Hormone Replacement
   - ☐ Other _____

HEADACHE CHARACTERISTICS:

4. Frequency of headaches - *On average, how often do you have headaches?*
   They occur _____ times each ☐ Day ☐ Week ☐ Month
   Are they increasing in frequency? ☐ Yes ☐ No
   They are more frequent on:
   ☐ Weekdays ☐ Weekends
   ☐ Spring ☐ Summer ☐ Fall ☐ Winter

5. Onset of each headache:
   Headaches typically begin: ☐ Gradually ☐ Suddenly ☐ Varies
   They usually begin in the: ☐ Morning ☐ Afternoon ☐ Evening ☐ Night
   How long before they reach maximal intensity? _____ ☐ Minutes ☐ Hours

6. Duration of the headaches:
   Headaches usually last (with medication) ____ ☐ Minutes ☐ Hours ☐ Days
   Headaches usually last (without medication) ____ ☐ Minutes ☐ Hours ☐ Days

7. Intensity of the headaches - H*ow bad are your headaches*?
   With medication: ☐ Mild ☐ Moderate ☐ Severe ☐ Incapacitating
   Without medication ☐ Mild ☐ Moderate ☐ Severe ☐ Incapacitating
   Headaches prevent activities ☐ School ☐ Work ☐ Household chores

8. Location of Headaches - *Where do you feel the pain during your headaches*?
   ☐ Left side ☐ Right side ☐ May be either side ☐ Both sides ☐ Other _____
   ☐ Forehead ☐ Temple ☐ Behind eye(s) ☐ Back of head ☐ Neck

9. Pain Type - *What does the headache pain feel like?*
   ☐ Pressure ☐ Stabbing ☐ Throbbing ☐ Other _____
   ☐ Tight band ☐ Burning ☐ Dull ache

10. Headache Triggers - *Do any of the following **bring on/trigger** your headaches?*

- ☐ Foods (specific food triggers will be discussed later in the questionnaire)
- ☐ Too much caffeine ☐ Not getting enough caffeine
- ☐ Hunger / Skipping meals ☐ Alcohol ☐ Wine
- ☐ Fatigue ☐ Too little sleep ☐ Too much sleep (sleeping in)
- ☐ During stressful times ☐ After stress (first day of vacation, weekend, after a test)
- ☐ Menstruation
- ☐ Exercise ☐ Sexual activity ☐ Coughing
- ☐ Prolonged computer work ☐ Weather changes
- ☐ Certain Odors ☐ Bright lights/sun ☐ Loud sounds

Other _____

11. Premonitory Symptoms - *Do you experience any of the following **before** your headache begins?*
- ☐ Mood changes ☐ Personality changes ☐ Other _____
- ☐ Change in appetite ☐ Food cravings
- ☐ Neck pain ☐ Fatigue ☐ No, I don't experience any of these

12. Aura Symptoms - *Do you ever experience any of these warning symptoms **before** your headache begins?*
- ☐ Bright lights / flashes of lights/ multi-colored lights (circle applicable description)
- ☐ Zig-zag lines ☐ Partial loss of vision / blurry vision / blindness (circle applicable)
- ☐ Numbness / tingling ☐ Paralysis
- ☐ Dizziness or vertigo ☐ Upset stomach / nausea ☐ No I don't have these

13. Associated Symptoms - *Do you experience any of these symptoms **during** your headaches?*
- ☐ Nausea / upset stomach ☐ Vomiting
- ☐ Bright lights/sun bothers you ☐ Loud sounds bother you
- ☐ Strong smells/odors bother you
- ☐ Dizziness / lightheadedness / vertigo (circle applicable description)
- ☐ Numbness or tingling
- ☐ Increased sensitivity of Scalp / Hair / Ears
- ☐ Eye tears ☐ Runny or stuffy nose
- ☐ Difficulty concentrating ☐ Mood changes / irritability

14. Alleviating Factors - *During a headache, what makes you feel the most comfortable?*
- ☐ Lying down / sleeping ☐ Being in a dark quiet room
- ☐ Keeping physically active ☐ Pacing back-and-forth
- ☐ Massage your head ☐ Tying something around your head
- ☐ Cold pack on your head/neck ☐ Hot pack on your head/neck

HEADACHE-RELATED DISABILITY:

15. Effect of headaches on ability to function:

a) During Milder headaches:
- ☐ I am able to function normally
- ☐ My ability to function is slightly decreased
- ☐ My ability to function is severely decreased
- ☐ I am totally bedridden

b) During moderate or severe headaches:
- ☐ I am able to function normally
- ☐ My ability to function is slightly decreased
- ☐ My ability to function is severely decreased
- ☐ I am totally bedridden

16. Doctor Visits for Headache – *How many times would you estimate that you have visited the following because of your headaches in the past 1 year?*
- ☐ Family physician _____
- ☐ Walk-in clinic _____
- ☐ Emergency department _____

17. How many days of work or school have you missed in the past 1 year because of headaches? _____

HEADACHE-RELATED INVESTIGATIONS

18. Previous Testing - *Have you had any of the following tests done to investigate your headaches? If yes, please indicate the approximate date and results:*

- ☐ CAT Scan _____
- ☐ MRI _____
- ☐ EEG _____
- ☐ Sinus X-rays _____ ☐ Neck X-rays _____
- ☐ Other _____

19. Previous Consultations - *Have you seen any of the following about your headaches? If yes, please give the name, and approximate date*:

- ☐ Neurologist
- ☐ Ear, nose and throat specialist
- ☐ Dentist
- ☐ Psychiatrist
- ☐ Pain Clinic
- ☐ Eye doctor
- ☐ Internal medicine
- ☐ Allergy specialist

_____

HEADACHE-SPECIFIC TREATMENT

20. Multi-Disciplinary Health Care - *Have you seen any of the following about your headaches?*

- ☐ Chiropractor
- ☐ Psychologist
- ☐ Physiotherapist
- ☐ Massage therapist
- ☐ Naturopath / homeopath / herbalist
- ☐ Other _____
- ☐ Acupuncturist
- ☐ Nutritionist

21. Headache-Related Purchases - *Have you purchased any of the following to try to treat your headaches?*

- ☐ Hot packs
- ☐ Cold packs
- ☐ Eye masks
- ☐ None of these
- ☐ Aromatherapy
- ☐ Naturopathic medicines
- ☐ Headache self-help book
- ☐ Other _____
- ☐ Herbs / Herbal supplements
- ☐ Anti-inflammatory rubs
- ☐ Mouth-guard

22. Headache Relief from Medications - *How long does it take before you become pain-free after taking your current headache medications?*

☐ Within 1 hour ☐ 1 – 2 hours ☐ > 2 hours ☐ I never become pain-free after medication

23. Current Headache Medications - *Please include all Over-The-Counter and Prescription Medications/Pain Relievers that you are **CURRENTLY** using to **TREAT** your headaches (do not include preventative medication)*:

Medication Name & dose	Average & Maximum used in 1 day	How many days used per month	Side-effects	% of time effective
i.e. Tylenol (325 mg)	Average 4; Max 10 tablets	10 days per month	None	
1.				
2.				
3.				
4.				
5.				
6.				

24. Current Headache Preventative Medications - *Please include all Prescription and Herbal Products that you are **CURRENTLY** using to **PREVENT** your headaches:*

	Medication Name	Dose	Side-Effects
1.	.....	.....	.....
2.	.....	.....	.....
3.	.....	.....	.....
4.	.....	.....	.....

25. Previously Tried Headache Medications - *Please include all Over-The-Counter and Prescription Medications that you have **PREVIOUSLY** used to TREAT(not prevent) your headaches but have stopped using:*

	Medication Name	Daily Dosage	Reason for Stopping
1.	.....	.....	.....
2.	.....	.....	.....
3.	.....	.....	.....
4.	.....	.....	.....
5.	.....	.....	.....
6.	.....	.....	.....
7.	.....	.....	.....
8.	.....	.....	.....

(If list exceeds 8, attach an additional paper with a list of all previously used headache pain medications)

26. Previously Tried Headache Preventative Medications - *Please include all Prescription and Herbal Products that you have **PREVIOUSLY** used to **PREVENT** your headaches:*

	Medication Name	Daily Dosage	Reason for Stopping
1.	.....	.....	.....
2.	.....	.....	.....
3.	.....	.....	.....
4.	.....	.....	.....
5.	.....	.....	.....
6.	.....	.....	.....
7.	.....	.....	.....
8.	.....	.....	.....

(If list exceeds 8, attach an additional paper with all previously used preventative medications)

HEADACHE-SPECIFIC QUALITY OF LIFE QUESTIONNAIRE

Please answer each of the following questions by checking the most appropriate answer (1 per question):

1. In the past 4 weeks, how often have headaches interfered with how well you dealt with family, friends and others who are close to you?

None of the time	☐	**Some of the time**	☐
Most of the time	☐	**All of the time**	☐

2. In the past 4 weeks, how often have headaches interfered with your leisure time activities, such as reading or exercising?

None of the time	☐	**Some of the time**	☐
Most of the time	☐	**All of the time**	☐

3. In the past 4 weeks, how often have you had difficulty performing work or daily activities because of headache symptoms?

None of the time	☐	**Some of the time**	☐
Most of the time	☐	**All of the time**	☐

4. In the past 4 weeks, how often did headaches keep you from getting as much done at work or at home as you would like?

None of the time	☐	**Some of the time**	☐
Most of the time	☐	**All of the time**	☐

5. In the past 4 weeks, how often did headaches limit your ability to concentrate on work or daily activities.

None of the time	☐	**Some of the time**	☐
Most of the time	☐	**All of the time**	☐

6. In the past 4 weeks, how often have headaches left you too tired to do work or daily activities?

None of the time	☐	**Some of the time**	☐
Most of the time	☐	**All of the time**	☐

7. In the past 4 weeks, how often have headaches limited the number of days you have felt energetic?

None of the time	☐	**Some of the time**	☐
Most of the time	☐	**All of the time**	☐

8. In the past 4 weeks, how often have you had to cancel work or daily activities because you had a headache?

None of the time	☐	**Some of the time**	☐
Most of the time	☐	**All of the time**	☐

9. In the past 4 weeks, how often did you need help in handling routine tasks such as every day household chores, doing necessary business, shopping, or caring for others, when you had a headache?

None of the time	☐	**Some of the time**	☐
Most of the time	☐	**All of the time**	☐

10. In the past 4 weeks, how often did you have to stop work or daily activities to deal with headache symptoms?

None of the time	☐	**Some of the time**	☐
Most of the time	☐	**All of the time**	☐

11. In the past 4 weeks, how often were you not able to go to social activities such as parties or dinner with friends because you had a headache?

None of the time	☐	**Some of the time**	☐
Most of the time	☐	**All of the time**	☐

12. In the past 4 weeks, how often have you felt fed-up or frustrated because of you headaches?

None of the time	☐	**Some of the time**	☐
Most of the time	☐	**All of the time**	☐

13. In the past 4 weeks, how often have you felt like you were a burden on others because of your headaches?

None of the time	☐	**Some of the time**	☐
Most of the time	☐	**All of the time**	☐

14. In the past 4 weeks, how often have you been afraid of letting others down because of your headaches?

None of the time	☐	**Some of the time**	☐
Most of the time	☐	**All of the time**	☐

HEADACHE MANAGEMENT QUESTIONNAIRE

Please rate each of the following seven questions by circling the most appropriate answer (one per question):

1. The overall effectiveness of treatment you currently use when headache attacks occur.

Very Satisfied	Somewhat Satisfied	Neutral	Somewhat Dissatisfied	Very Dissatisfied	Does Not Apply to Me
☐	☐	☐	☐	☐	☐

2. The overall effectiveness of treatment you currently use to prevent headache attacks from occurring.

Very Satisfied	Somewhat Satisfied	Neutral	Somewhat Dissatisfied	Very Dissatisfied	Does Not Apply to Me
☐	☐	☐	☐	☐	☐

3. The overall effectiveness of your current treatment on the frequency of your headache symptoms.

Very Satisfied	Somewhat Satisfied	Neutral	Somewhat Dissatisfied	Very Dissatisfied
☐	☐	☐	☐	☐

4. The overall effectiveness of your current treatment on the severity of your headache symptoms.

Very Satisfied	Somewhat Satisfied	Neutral	Somewhat Dissatisfied	Very Dissatisfied
☐	☐	☐	☐	☐

5. Your ability to self-manage headache symptoms.

Very Satisfied	Somewhat Satisfied	Neutral	Somewhat Dissatisfied	Very Dissatisfied
☐	☐	☐	☐	☐

6. Your ability to avoid conditions that may cause headache symptoms to occur.

Very Satisfied	Somewhat Satisfied	Neutral	Somewhat Dissatisfied	Very Dissatisfied
☐	☐	☐	☐	☐

7. The amount of money you spend on headache symptom treatments.

Very Satisfied	Somewhat Satisfied	Neutral	Somewhat Dissatisfied	Very Dissatisfied	Does Not Apply to Me
☐	☐	☐	☐	☐	☐

HEADACHE DISABILITY QUESTIONNAIRE

Please indicate the number of days over the past 3 months that your headaches affected the activities described in questions 1 to 5 below.	
Questions	**Number of Days**
How many days in the last 3 months did you miss work or school because of your headaches?	
How many days in the last 3 months was your productivity at work or school reduced by headaches?	
How many days in the last 3 months did you not do housework because of your headaches?	
How many days in the last 3 months was your housework productivity reduced by 50% or more because of your headaches?	
How many days in the last 3 months did you miss family, social or leisure activities because of your headaches?	

A. How many days in the last 3 months (90 days) did you have a headache? _____

B. On a scale of 0 to 10 (with 0 = no pain and 10 = pain as bad as it can get), what was the average severity of your headaches over the last 3 months? _____

Headache-Related Nutrition Questionnaire

1. Are you aware of any specific food triggers that can cause your headaches? Please list:

_____
_____
_____
_____

2. If you are aware of food triggers, how did you become aware of your triggers? Please check all that apply, and provide detail if necessary:

- □ Observation/instinct _____
- □ Trial and error _____
- □ By completing food/symptom diaries _____
- □ Suggestion from MD, dietician, naturopath _____
- □ Other (provide details) _____

3. Have you made any changes to your eating behaviours to help control your headaches?

- □ Strictly avoid specific trigger foods (list foods): _____
- □ Try to avoid certain trigger foods, but tend to be inconsistent (list):
  _____
- □ Reduced my caffeine intake from _____ to _____
- □ Changed meal frequency (provide details; how consistently?) _____
- □ Added breakfast: (yes/no; how frequent?) _____
- □ Improved my hydration (how much more fluid, what types?): _____

4. Please describe your weight:

- □ My weight has been fairly stable (within 10 lbs) in my adult life
- □ My weight has increased over the years
- □ My weight has gradually declined over the years
- □ My weight tends to fluctuate up and down

5. Do you diet, follow weight loss programs, or visit weight loss centres (e.g. Weight Watchers, low carb, Bernstein, Fuel for Life, Atkins, etc.)?

- □ Never or almost never
- □ Yes, I've tried a few diets, diet centres, or programs
- □ Frequently. I usually try a few diets or programs each year
- □ I'm constantly dieting

6. Do you currently, or have you ever tried supplements (vitamins, minerals, herbs) to help control your headaches? Please list:

SUPPLEMENT	DOSE (IF KNOWN)	LENGTH OF TIME TAKEN	IMPACT

Physical Activity Questionnaire

Do you engage in regular physical activity? ☐ **Yes** ☐ **No**

Do you have access to a fitness gym? ☐ Yes ☐ No ☐ Commercial ☐ Home ☐ Private studio ☐ Condominium ☐ Work ☐ Other ……..	Do you have a personal trainer/fitness coach? ☐ Yes ☐ No Name/contact info (if desired): ……

Equipment/Facilities Available (whether currently used or not):

Cardiovascular	Strength Training	Sports Equipment/Facilities
☐ Treadmill	☐ Free Weights	☐ Squash/Tennis courts
☐ Stationary Bike	☐ Machines	☐ Golf Course/range
☐ Track	☐ Resistance Bands	☐ Skiing
☐ Elliptical	☐ Physio balls	☐ Pool
☐ Other:	☐ Other:	☐ Other:
……	……	……..

Current Physical Activities:

Cardiovascular			Strength		
Modes/Type of Training:			**Modes of Training:**		
☐ Treadmill ☐ Stationary Bike ☐ Walking/Jogging	☐ Swimming ☐ Elliptical ☐ Sports (please list): ……..		☐ Machines ☐ Free Weights ☐ Other (please list): …….		
How many minutes per day?	☐ 10 to 20 ☐ 20 to 30 ☐ 30 to 40 ☐ 40 to 60 ☐ 60+		**How many minutes per day?**	☐ 10 to 20 ☐ 20 to 30 ☐ 30 to 40 ☐ 40 to 60 ☐ 60 +	
How many times per week?	☐ 1 ☐ 2 ☐ 3 ☐ 4	☐ 5 ☐ 6 ☐ 7 ☐ More ……..	**How many times per week?**	☐ 1 ☐ 2 ☐ 3 ☐ 4	☐ 5 ☐ 6 ☐ 7 ☐ More ……..
Intensity:	☐ High ☐ Moderate ☐ Low ☐ HR Zones: High ……. Low ……. Avg ……. ☐ Interval Training: Ratio high:low ……..		**Set Routine:**	☐ Yes ☐ No Sets ……..….. Reps ……. Rest between sets ……..…	

Sports You Participate In:

Activity	Yrs Participated	Highest Level of Competition	Current Level of Competition
		☐ Recreational ☐ Competitive ☐ Professional	☐ Recreational ☐ Competitive ☐ Professional
		☐ Recreational ☐ Competitive ☐ Professional	☐ Recreational ☐ Competitive ☐ Professional
		☐ Recreational ☐ Competitive ☐ Professional	☐ Recreational ☐ Competitive ☐ Professional
		☐ Recreational ☐ Competitive ☐ Professional	☐ Recreational ☐ Competitive ☐ Professional

Psychology Questionnaire – Headache Program

STRESS MANAGEMENT:
Please describe any recent life stressors (e.g. health, relationships, financial, work)?

How do you cope with stress in your life (e.g., physical exercise, meditation, relaxation)?
How helpful are these techniques at managing your current level of stress?

Is it often hard for you to relax and unwind? ☐ Yes ☐ No

FUNCTIONAL ASSESSMENT:
In the <u>past month</u> have you….

Yes	No	
☐	☐	Had periods of time when you feel down or depressed?
☐	☐	Felt less interested in doing things you normally like to do?
☐	☐	Head periods of excessive energy, mood swings, increased irritability and/or loss of concentration?
☐	☐	Been worrying excessively about a number of things?
☐	☐	Felt very nervous or anxious or suddenly experienced a lot of physical symptoms (e.g., heart racing, sweating)?
☐	☐	Had a fear of losing control of yourself or "going crazy"?
☐	☐	Avoided social situations for fear of what others may think or say about you?
☐	☐	Been afraid of leaving your home alone, or being home alone?
☐	☐	Had repeated thoughts or images in your head that are difficult to dismiss?
☐	☐	Felt compelled to complete certain behaviours repeatedly (e.g., checking to make sure you locked the doors, washing your hands again an etc.)?
☐	☐	Thought a lot about or relived an upsetting event from the past?
☐	☐	Found yourself preoccupied with food, weight or body image?
☐	☐	Been concerned about your use of alcohol or medication/drugs?

Have you been in therapy before or received any prior professional assistance for emotional, psychological relationship issues? ☐ Yes ☐ No If yes, please describe, starting with most recent/current

Dates	Duration/# of sessions	Physician/Therapist	Type of Therapy/Treatment (marriage counseling, group sessions, etc

Have you ever been diagnosed with a psychological condition (e.g. clinical depression)? ☐ Yes ☐ No
If yes, please describe.

Thank you for taking the time to complete this form. Your responses will be treated as private and confidential.

PATIENT OPINIONS/QUESTIONS:

1. What type of headache(s) do you think you have?

_____

_____

2. Do you have any specific concerns/fears about your headaches?

_____

_____

_____

3. What specific questions do you have for Dr. Gladstone and the Headache Program Team?

(a) _____

(b) _____

(c) _____

(d) _____

(e) _____

(f) _____

(g) _____

Thank-you for taking the time to complete this important questionnaire.

Submit

NOTE: If you have trouble submitting the questionnaire or receive an error message, please save the questionnaire to your desktop and email it to canadaforms@ccf.org.

PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL ADVISORY COMMITTEE (PTAC)

PRELIMINARY REVIEW TEAM (PRT)

CONFERENCE CALL WITH THE AMERICAN ACADEMY OF NEUROLOGY (AAN)

Wednesday, January 24, 2018

10:00 a.m.

PRESENT:

ROBERT BERENSON, MD, PTAC Committee Member
RHONDA M. MEDOWS, MD, PTAC Committee Member
KAVITA PATEL, MD, MSHS, PTAC Committee Member

LOK WONG SAMSON, PhD, Office of the Assistant Secretary for Planning and Evaluation (ASPE)
MARY ELLEN STAHLMAN, ASPE

ANJALI JAIN, MD, Social & Scientific Systems, Inc. (SSS)

AMANDA BECKER, Senior Director, Policy and Practice Innovation, AAN
JOEL M. KAUFMAN, MD, Medical Director, Neurology Resident Teaching Clinic, Rhode Island Hospital, and Clinical Professor of Neurology, Alpert Medical School, Brown University
AMANDA NAPOLES, Program Manager, Payment Programs, AAN

P R O C E E D I N G S

[10:03 a.m.]

DR. BERENSON: All right. So let's start with the PRT (Preliminary Review Team), the members of the PTAC (Physician-Focused Payment Model Technical Advisory Committee) who are on the Committee that's reviewing the proposal.

I'm Bob Berenson, a former internist, and I'm at the Urban Institute.

DR. SAMSON: Kavita, would you like to introduce yourself?

DR. PATEL: Sure. Kavita Patel, an internist at Hopkins and a fellow at the Brookings Institution.

DR. SAMSON: And from ASPE (the Office of the Assistant Secretary for Planning and Evaluation), this is Lok Wong Samson. I'm a policy analyst supporting the PTAC.

MS. STAHLMAN: And this is Mary Ellen Stahlman. I'm also an analyst in ASPE, and the PTAC Staff Lead.

DR. SAMSON: And then turning to the AAN (American Academy of Neurology), Amanda, would you like to start first?

MS. BECKER: Sure.

MS. NAPOLES: I know it's confusing. We've got two Amandas on our team. My name is Amanda Napoles. I am the Program Manager for Payment Programs at the AAN.

MS. BECKER: And I'm the other Amanda. Amanda Becker, Senior Director of Policy and Practice Innovation at the AAN.

DR. KAUFMAN: Hi. This is Joel Kaufman. I'm not Amanda. So I'm a general neurologist. I'm mostly retired. My main activity now is teaching and learning from neurology residents. I'm the Medical Director of the Neurology Resident Clinic, Rhode Island Hospital, and Clinical Professor of Neurology at the Alpert Medical School at Brown.

Just to give a little more background for me, I practiced in a large multispecialty group in Worcester, Massachusetts, for many years. I was Medical Director at Fallon Community Health Plan, which was one of the three original Medicare demonstration projects for seniors and actually the only one that survived, and I was Medical Director there from [1988] to 1997.

I then went to Rhode Island. I was

Executive Director of a 950-physician PHO (physician hospital organization), and Senior Vice President for Care Coordination at Life Span, which is Rhode Island Hospital, Miriam, Newport, and Bradley Hospitals. I've been active with the AAN for many years, a long time, with service on medical economics, quality, payment policy, and payment alternative committees and work groups.

I want to thank the PRT and the staff from ASPE for reviewing our proposal critically and for taking this opportunity to question us, so thank you.

DR. SAMSON: Thank you, Dr. Kaufman.

Did I hear somebody else beep in? Was that Rhonda?

DR. MEDOWS: This is Rhonda Medows, yes. Thank you.

DR. SAMSON: Would you like to introduce yourself to the --

DR. MEDOWS: Sure. I'm Rhonda Medows. I'm a physician. I am also the Executive Vice President for Population Health at Providence St. Joseph Health.

Thank you.

DR. SAMSON: So before we start with the call, we just want to remind everyone this call will be transcribed. So it would be really helpful if you could say your name before you speak so that the transcriptionist will know who's speaking.

DR. BERENSON: So I guess I should take the lead. I'm the Chair of this PRT, but we pretty much function interchangeably. But we sent you back -- well, Lok sent you back an email, which sort of was focused on the fact that we were confused about the proposal, and then your letter response suggested -- well, absolutely clarified what the intent was but seemed to be at some variance to what the proposal was. And I'll just try to articulate our confusion.

There were clearly references to -- in many places -- well, clearly to the definition that you emphasized about -- I'm trying to find it right now -- undefined -- oh, yeah -- undiagnosed, difficult to diagnose, or poorly controlled headaches as a primary objective of the project, but then there were probably two dozen references to complex headaches with citations only to migraine and cluster headaches, and then in

particular, the appendix, which had the ICD-10 (10th Revision of the International Statistical Classification of Diseases) codes, were only migraine and cluster headaches.

So, the response in your letter on page 2, which laid out the whole range of headaches that seniors would get, were only vaguely referenced in the proposal, although in some places -- which is why some of us were confused about really what the focus of the proposal was -- but none of the ICD-10 codes relevant to those diagnoses were actually in the appendix.

So, fundamentally, we were confused, and it seems in your letter response that this is a much broader concept than just focusing on cluster and migraine.

So, I think the first thing to do is to just clarify in words and conversation what your objectives are, and were we -- I mean, settle the confusion that we had. Tell us what it is that you're hoping to do, that you want to do, and then we can try to figure out how -- whether you need to sort of revise the proposal or whether we understand it well enough.

So, if I could turn to -- is it Dr. Kaufman [who] should be the one who speaks to it, or whomever from AAN should speak to our confusion?

DR. KAUFMAN: I'll take -- this is Joel. I'll take a stab at it first.

DR. BERENSON: Okay.

DR. KAUFMAN: So, thank you for the questions.

Our aim is to attract to the neurologist or headache specialist -- and just for the sake of this conversation, I'll use the word "neurologist" rather than just "neurologist and headache specialist" about this -- I'll use "neurologist."

So the idea is that the patients that are most appropriate for the neurologist’s expertise to be seen and referred to the neurologist, and patients that have less complex headaches, those that have been clearly diagnosed, are not difficult to treat, would stay with the primary care physician. So that's our goal.

Unfortunately, most of the literature is about migraine, and there's not as robust a [sic] literature about headache treatment and processes of care [as] one might like. But again, our goal

is to concentrate on those patients that are undiagnosed, difficult to treat, and difficult to diagnose.

The ICD-10 codes, as you note, really concentrate on migraines and other types of headaches, but there is a code. And it's sort of a catch-all, and in my experience, a lot of physicians use this. If you have the list in front of you, it's G43.C1, and it's “periodic headache syndromes in child or adult, intractable.” So that would be a lot of -- the patients that we would see would fall into that.

Again, migraine and clusters, particularly in ICD-10, was expanded to include a lot of subtle --

DR. BERENSON: Well, we thought we found some G44 codes that were relevant to at least some of the examples you provided. Is that not the case?

DR. KAUFMAN: No, that's the case also. If you're talking specifically about migraine, intractable migraine, we have cluster, which again is another -- not a migraine.

DR. BERENSON: Right.

DR. KAUFMAN: But you have tension headaches. You have migraine, and you -- particularly for those that aren't diagnosed, I mean, I think as we all know, physicians tend to pick a code that's close but may not be what the patient, after a further evaluation has -- is that -- does that answer your question?

DR. BERENSON: Well, it sort of does.

Lok, you looked more carefully at the ICD-10 codes than I did. I mean, I guess the question is -- so you're basically saying that all the examples you gave in your letter -- hypnic headaches, medication overuse headaches --

DR. KAUFMAN: Mm-hmm.

DR. BERENSON: -- headache with various comorbidities, giant-cell arteritis, et cetera -- don't have specific codes. They're just using that sort of all-encompassing code that you're referencing?

DR. KAUFMAN: Well, giant-cell arteritis would have its own code.

DR. BERENSON: Right.

DR. KAUFMAN: Okay. So the question of giant-cell arteritis is making the diagnosis

correctly.

DR. BERENSON: Right.

DR. KAUFMAN: Right. So once the diagnosis is made correctly, the patient is treated, and in our model, that would not proceed through our Category 2 or even our -- or necessarily our Category 3. So that would be a question if a patient comes that may have been diagnosed with migraine or cluster, you know, a trigeminal type of headache, unilateral headache in an older person, and the key is to make that diagnosis of the giant-cell arteritis.

And again, another example might be someone that comes with a headache that's diagnosed as [a] tension headache. We might diagnose a headache related to cervical disease or a triple neuralgia treated --

DR. BERENSON: Right.

DR. KAUFMAN: -- would fall out of our APM (alternative payment model).

DR. BERENSON: It would fall out of your APM.

DR. KAUFMAN: Right. Cervical -- you know, a cervical-related headache is not one of the

things that we propose to continue to follow in our APM.

DR. BERENSON: Well, I guess that's the question, is “why would it fall out as opposed to fall into?” Have this be a -- one, to be broader and, two, to include new onset headaches in the Medicare population. I guess I don't understand why it would fall out rather than fall in.

DR. KAUFMAN: Because the feeling of our group is it's not a primary headache. It may have head pain, but talking with our --

DR. BERENSON: I see.

DR. KAUFMAN: -- headache specialists, that would be not one of the groups that -- it certainly falls in -- within the ICD-10 codes that we did.

DR. BERENSON: It would? I mean, wouldn't those patients be maintained with basically using the ICD-10 symptom? Would they be prematurely and incorrectly assigned to a migraine ICD-10 code? Then you diagnose cervical disease, and there -- I mean, so what typically happens?

DR. KAUFMAN: Right. So in our group as we prepared this, we had a lot of discussion about

this, and we went back and forth quite a bit. And the thought was to concentrate on -- I'm going to keep going back to it, but to the undiagnosed, difficult to diagnose, and difficult to treat.

So the thought was that if it's not a -- I'm going to use the term "primary headache disorder" -- that in our model -- that would not be continued in our APM.

And we had -- we had a lot of discussion back and forth, and our consensus -- not unanimous -- our consensus was that items that are not primary headache disorders should not remain in here.

DR. BERENSON: I see.

DR. KAUFMAN: And part of it --

DR. BERENSON: So presumably, the management of those patients would be moved on to somebody else, but the diagnosis of those patients often would rest with the headache specialist, right?

DR. KAUFMAN: Absolutely, yes. Absolutely, yes.

DR. BERENSON: Well, I don't -- would somebody else from the PRT want to pick this up? I

don't sort of get the logic, but I understand you had a division within your group.

So, let's go back to my example, and then I'll turn to Kavita or Rhonda. If a patient comes in with headaches of undetermined etiology and are getting an evaluation, let's say, from another neurologist, how would that be coded until a definitive diagnosis is made that it is temporal arteritis or associated with medication overuse or whatever it might be? How would that -- what would be the ICD-9 -- ICD-10 designation until that definitive diagnosis is made? Or is there no consistent pattern?

DR. KAUFMAN: This is Joel.

Well, it would be to the best of the ability of the neurologist to make that -- to pick an appropriate code.

DR. BERENSON: But are there opportunities within the ICD-10 coding structure to just use a code for symptoms without an etiology? I mean, there are symptom codes as well. Would they be maintained that way, or would they have to be prematurely assigned to another diagnostic category, if you understand my question?

DR. KAUFMAN: I do. I'm not sure I have an adequate answer to your question.

DR. BERENSON: Okay.

DR. KAUFMAN: I'll turn to Amanda or Amanda.

MS. BECKER: Amanda Becker.

I know you have a little bit more understanding of the coding. Do you have any input here that we may want to circle back with? We have our coding expert on --

DR. BERENSON: Maybe if we don't have an answer today, we can put our heads together and try to figure that -- we have a much better idea of what you're trying to accomplish, I think -- that you want to include the diagnoses that would be ongoing.

I mean, correct me if I'm wrong. The diagnoses that are primary headache or neurology diagnoses, that you would be treating and monitoring that patient over time rather than make the diagnosis and just refer to the appropriate other physician, who would then be monitoring. You're looking for neurologic diagnoses associated with headache, not -- and focusing more on the

long-term management than on the initial diagnosis, is the way I would interpret what your committee is telling us.

DR. KAUFMAN: Yes. This is Joel.

That's what I meant to say. You said it well, but the idea is to focus on those patients with "neurologic," in quotes, “primary headache disorders” that are -- that require the expertise of the neurologist because of their difficulty to control, either based on patient response or comorbidities, lifestyle issues or things like that, where the neurologist and the support that the neurologist with this new payment model will take advantage of, can address and help the patients do better.

DR. BERENSON: Okay. Rhonda or Kavita, do you want to pursue this anymore? Are you -- any other clarifications?

DR. PATEL: No. No. It -- Bob, maybe if we're getting into some of the other aspects of the model -- I'd still like to hear Joel or Amanda or Amanda. I'm struggling a little bit with how, sort of in real time, kind of what -- what this would look like from kind of the initiation of

[unintelligible] -- you know, kind of from the referral.

And then you mentioned neurologists or headache specialists -- Is there any reason that general neurologists could not do this? Do you think that there need to be people who are neurologists who have a particular training in headache specialty?

DR. KAUFMAN: Sure. This is Joel.

General neurologists are able to care for the vast majority of headache patients that are referred to them, and I will say that internists, family practice doctors, others are able to take care of the vast majority of headache patients that they see. So those that require the referral to a general neurologist can take care of the vast majority of those patients.

I mean, there are clearly some patients that require further referral, but my experience is there are not a lot of those that may need to see a specific headache specialist.

And I apologize. The first part of your question, I forgot already.

DR. PATEL: I'm just trying to understand.

Well, maybe we'll get into it when we understand the payment a little bit because I -- it strikes me that the typical clinical pattern is usually these patients -- well, one of two pathways. These patients either kind of get immediately referred because somebody, usually a primary care clinician, can't or doesn't feel comfortable dealing with it, or they go through, I think as you mentioned in the proposal, kind of either misdiagnosed or inappropriate treatments, et cetera, and then they land into a neurologist.

And so I'm just trying to understand kind of -- kind of what the -- since all these diagnoses are -- tend to cluster around migraines, et cetera, would it be, you know, the actual diagnosis that would, quote/unquote, “trigger the payment model?” Would it be the patient's -- you know, kind of like a shared decision-making process on a first visit? How would -- how would Medicare as an entity, for example, know that -- how this patient is in this particular payment model?

DR. KAUFMAN: There's often a long wait time -- years. I think it's about eight years until patients are referred, who have difficult to

control headaches, to see a headache specialist.

And one of the things that we see now, are patients that come in with medication overuse syndromes or transformed migraines. [Unintelligible] an ICD code -- ICD-10 code for medication overuse, but patients that have transformed migraine, patients who are just taking too much triptans, particularly older patients where it's not the best thing to do.

So, there's just a long time until those patients are referred. And so, the thought here is that the neurologist will have a relationship with his or her referral sources and will grease the wheels.

Right now, there's clearly access issues to see neurologists, so working with the primary care physicians, and often, as you're all aware, the internist, the family practice doc has limited time.

We see a lot of referrals now from -- the patient is in for a visit or a routine exam. Patient mentions headaches; the plan, refer to a neurologist. So hopefully working with the primary care physician can give some support for those

patients to stay with the primary care, which frees up access for the neurologist and gets patients in more quickly.

Clearly it has to be patient-centered, shared decision-making with the patients. The patients have to opt-in to this program. They have to agree to get their headache care with the neurologist on that team, including the primary care physician.

So we do see -- we do see a process that's similar to the medical home neighbor process, where the practices work together.

DR. BERENSON: Would you envision that a neurologist would actually refer to the headache specialist for difficult cases or not? I mean, is it -- how many of these -- I mean, if in fact there was a good payment model, would you envision a few hundred of these around the country, a few thousand, tens of thousands? I mean, what's the delivery model look like? That there are neurology practices, and then there are certain designated headache specialty, headache centers is what I'm understanding, which have a different payment model. Is that -- so if you could somehow try to

address this, if you're in Rhode Island, would there be one or two of these in the state, or would there be -- any neurologist could qualify for it? How would you see that happening?

DR. KAUFMAN: So actually, in Rhode Island, which is a small state, but there's a lot of neurologists there.

When I first went into practice, I practiced in Worcester, Mass. There was about 10. In 1981, there was about 10 neurologists in Rhode Island. Now there's, I think, over 50, but there’s a solo neurologist that has a very robust headache program there. And there's -- there aren't any academic headache programs in Rhode Island.

When we developed the model, we wanted to make sure it was flexible because it's very important for us to support neurologists that are in solo or small practices, but also to have this model work for large headache programs with dedicated headache specialists.

The headache-oriented people, neurologists that work on this, I mean, most of us that work on this are general neurologists, but we had someone from Austin, Texas, who runs a large headache --

dedicated headache program, and we had a solo neurologist in Pennsylvania who are a small -- neurologists have a small group in Pennsylvania -- that's also a headache specialist. So we wanted to make sure this was flexible, scalable. There aren't tens of thousands of neurologists, but hopefully, there will be many, many that find this program attractive and will participate.

Even in places like Boston, there are relatively few headache patients that end up going to large dedicated headache centers.

I live in Worcester. I practice in Rhode Island. But in Worcester, for example, there's a solo neurologist, Herb Markley, that's a headache specialist, has run that program for many, many years, and he's fairly selective, consistent with the model we have here in terms of who he accepts to see. Partly to maintain access and to maintain relationships with referring physicians. He doesn't want to steal patients. He wants to support the primary care practices, the same as Gary L'Europa, who is the one in Rhode Island, again, has just a very good program and wants to make sure he sees patients that he feels he can

help. But it's a small percent of the total headache patients that are seen by neurologists that go to the specialized headache centers.

DR. BERENSON: Somebody needs to go on mute because there's some walking and paper shuffling or something going on. I'm not sure who that is.

So you wouldn't -- so just following up, then, you would not see that the majority of neurology practices necessarily would become these headache -- centers of headache expertise, I guess, for lack of a better term?

DR. KAUFMAN: Well, I would see --

DR. BERENSON: Or you're not sure?

DR. KAUFMAN: Hopefully -- sorry for interrupting.

DR. BERENSON: Yeah, go ahead.

DR. KAUFMAN: Hopefully, the majority of neurologists will participate in this APM.

DR. BERENSON: I see. And would -- and presumably -- well, let me ask the question because you've addressed it a little bit. I read somewhere, but, do you envision that perhaps internists could develop a specialization in managing headaches and

could qualify also?

DR. KAUFMAN: Yes. There are some headache specialists around the country now, and some of the early headache specialists -- Seymour Diamond, for example, was an internist. So, we're hopeful that this model will work for neurologists and headache specialists whether they're neurologists or internists, some ENT (ear, nose, and throat) practices that do a lot of specialized headache work. So yes, we're -- and that's why we wanted to make it flexible.

DR. BERENSON: And that's a -- okay. And there is an educational postdoc kind of program -- I mean, I forget the language that you used -- for getting the expertise and essentially getting a credential, basically?

DR. KAUFMAN: There is -- there are very few physicians that participate in that. It's not a generally recognized board.

DR. BERENSON: Okay.

DR. KAUFMAN: But neurologists by the nature of their training spend a lot of time studying headaches.

DR. BERENSON: Got it.

DR. KAUFMAN: In our clinic with the residents, upwards of a third of the patients who are referred are referred for headaches.

DR. BERENSON: Rhonda, Kavita, back to you.

DR. MEDOWS: So can you hear me? I'm having trouble hearing you, but can you hear me? This is Rhonda.

DR. BERENSON: Yes.

DR. MEDOWS: Okay. I think the major questions that I had were answered, the best I can tell. My questions were going to be, you know, are headache specialists -- are all headache specialists neurologists? But then I heard the comment about some of the internists being able to train also as a headache specialist. That's correct, right?

DR. KAUFMAN: Yeah.

DR. MEDOWS: So how about pain management physicians? Can they also be a headache specialist, or is that separate?

DR. KAUFMAN: That's a good question. I'm not aware. There's necessarily not a reason they couldn't be.

Our data shows, though, that 80 percent of patients with headache, you know, migraine or tension-type headaches, some headaches, aren't cared for by their primary care team, and that's why we want to concentrate on the patients that are more difficult to diagnose, treat, or manage.

DR. MEDOWS: Okay. And did we talk about what you estimate the patient volume would be for each of the headache specialists in this model, in Medicare? Do you have an idea, a number?

DR. KAUFMAN: Well, we're hoping to meet the minimum. We have -- we've talked with some practices in -- I'll turn to Amanda Napoles. I don't have an exact estimate, but one of the reasons we selected headache, was our research showed there would be adequate numbers to make this work to help neurologists or headache specialists get to the threshold, the 25 percent, 50 percent threshold using this APM and other APMs that we hope to put forth in the next month.

DR. MEDOWS: Under your payment model, was the payment applied only to the headache specialist, or can some of your physician partners, who are not headache specialists, also share in the

upside and downside?

DR. KAUFMAN: That's another question we struggled with, and at this point, the payments would go to the neurologist or the headache specialist.

DR. MEDOWS: Okay. Thank you. Thank you very much.

DR. KAUFMAN: Thank you.

DR. BERENSON: I'll pick up on one.

Kavita, do you have one? I'll pick up on one if you don't.

DR. PATEL: No. I just -- if you -- I can ask about -- I wanted to just get to the $4,000 question at some point.

DR. BERENSON: Oh, yeah. Okay. Well, let me ask mine because we're in the personnel topic.

I mean, I want to understand a little more about the function and credentials of the advanced practice providers.

I mean, presumably, one of the things that I read was that it would sort of permit a headache physician to see more patients because there's complementary professionals involved. But give me a sense of who that person is, what they're doing,

because the [unintelligible] -- or the payment model would have to be more to cover more people.

So tell me about the APP (advanced practice providers) person and whether there's some real-world examples.

DR. KAUFMAN: There are nurse practitioners and physician assistants that work in -- with physicians, taking care of patients with headache or other neurologic conditions, and the idea is to use everyone's expertise to the maximum.

When I go to my physician, when I have a problem, I like to see my MD when appropriate and see my nurse practitioner when appropriate, and that's the idea here. The plan is that the patient sees the physician for the first round, but a lot of the headache management, particularly for difficult-to-control patients, revolves around medication management, lifestyle intervention, following up on studies. You know, sleep disorders turn out to be an increasing issue --

DR. BERENSON: Mm-hmm.

DR. KAUFMAN: -- with patients with chronic headache. Medication management, weening patients who have medication overuse headaches is a

difficult long-term issue. Those are the most difficult patients to manage now, in my experience, and we want to take advantage of all the clinical expertise.

I'm going to say my personal opinion now is -- and I think we state this in the response, but the nurse practitioners and the physician assistants are clinicians, and our goal is that they function as clinicians.

On the other hand, in smaller practices, the headache care coordinator, maybe the physician, maybe the nurse practitioner, or maybe other office staff that can work with coordination follow-up, gathering headache -- the headache logs and other things. So again, they're very important and critical and right now not compensated time for physicians.

DR. BERENSON: So would it be fair to summarize that as saying that the APP, the nurse practitioner -- are these largely nurse practitioners with the occasional PAs (physician assistants), or there's a mix?

DR. KAUFMAN: Yes.

DR. BERENSON: Okay. Are [they] focused

mostly on management and not on the initial -- or the undiagnosed or misdiagnosed patient? That's primarily the physician who's taking that on, and once there is a correct diagnosis, then it becomes a much larger role for the APP. Is that basically correct?

DR. KAUFMAN: Yes.

DR. BERENSON: Okay. Kavita, go.

DR. PATEL: And this might be pretty straightforward, but I think I just wanted to clarify. In the proposal -- and we put this in our -- hopefully, it's not catching you too off guard. You had cited a $4,000 average cost across all settings for a patient visit in this kind of complex area. Is that -- was that per a single patient visit, or was that over a certain period of time for total spending, including hospitalization? We just wanted to get a better sense of that 4,000.

DR. KAUFMAN: I'm going to let Amanda Napoles answer the question, but I will say from the -- from the moment we put that in, we knew that the language of how we did that was not as best [as] it could be. But I'll let Amanda answer that one.

MS. NAPOLES: Hi. This is Amanda Napoles.

So beyond what we've provided in our responses, I'm not sure how much further we can clarify. It is a patient visit data point, but perhaps if we're still having questions about it after this call, we can schedule some time with our data scientist to kind of get more at the root of where that number came from and how he came up with that number.

DR. BERENSON: I think it would be important for us to -- for you guys to go do that because I'm envisioning then that every visit has an MRI (magnetic resonance imaging) and lots of testing, and there's a facility fee. I mean, I can't imagine how you get to 4,000 without just assuming everybody is having the whole book of everything thrown at them during a visit.

So, it would be very helpful for us to know because I'm sympathetic with the language in the proposal suggesting that neurologists who actually know about headaches might be much more efficient and only order advanced imaging and other things when it's necessary as opposed to the scattershot approach that many other physicians

would probably be taking.

So, I am sympathetic to that, but we need to understand the 4,000 to make -- to really know what's now being done --

DR. KAUFMAN: Right.

DR. BERENSON: -- to --

DR. PATEL: And I've looked at the --

DR. BERENSON: -- assess the potential of the reduction.

Go ahead, Kavita.

DR. PATEL: No, I mean, I just -- I guess I'm just confused. I mean, they kind of extracted what's basically kind of a definition of expenditures in MEPS (Medical Expenditure Panel Survey), which I know I could -- Bob and myself are pretty familiar with. But, it still states that it looks like it's for an outpatient visit, so I'm just still struggling as to what, what really -- I'm pretty familiar with complex outpatient visits in my own institution, and I just can't figure out how this 4,000 comes together.

DR. KAUFMAN: Yeah. My understanding is it's -- the 4,000 is a yearly -- yearly cost for outpatient services --

DR. BERENSON: Okay.

DR. KAUFMAN: -- related to headaches.

But, Dr. Berenson, the American Academy of Neurology for a long time has had a guideline that states that patients with tension or simple migraine headaches, with no findings on [an] exam, should not have any imaging, none.

DR. BERENSON: Right, right.

DR. KAUFMAN: And unfortunately, I can't tell you the last time we've had a patient that's been referred that hasn't had at least two imaging studies.

DR. BERENSON: Yep. With diagnosable migraine. I mean, your --

DR. KAUFMAN: With simple classic migraine.

DR. BERENSON: Yeah, yeah.

DR. KAUFMAN: I mean, it's just -- and every time -- at Rhode Island Hospital, they have a program where they track the amount of radiation for the patients that go through the system, and they had a patient with -- with chronic headache, tension-type headache, who's had over 50 imaging studies -- 50.

DR. BERENSON: Yeah.

DR. KAUFMAN: I mean, it's just -- it's incredible.

DR. BERENSON: Yeah, yeah. No, it is incredible, and I wouldn't be surprised if in the -- if it turns out it's annual, as you suggest, 4,000, I wonder how many scans are being done. Mostly MRIs, I assume, but then probably inappropriate CT scans in there as well --

DR. KAUFMAN: Yes.

DR. BERENSON: -- with all the radiation.

How are we doing on time here? We are at 10:39.

Any other questions before we try to talk about how we should proceed? Kavita, Rhonda, do you have any other immediate questions?

DR. MEDOWS: I have no additional questions. Thank you.

DR. PATEL: No, I'm good.

DR. BERENSON: So, I want to go back to the issue of all of these other comorbidities.

The letter response, by the way, referred to somewhere in the appendix where there was a listing of comorbidities, and we couldn't find it.

So, it's that issue of, are we dealing really with complex headaches that are managed and therefore if a -- so here's the question. If a primary care physician refers a patient to one of these headache centers and it turns out the patient had cervical spine disease with headaches and that doesn't meet the ICD-10 listing that you have, does that just get paid under classic E&M (evaluation and management)? I mean, just the regular fee schedule codes, and the only -- and you have to qualify with one of those ICD-10 conditions to be eligible for the payment? And so some of the most valuable work that you're doing is actually not part of the process? I guess that's the inconsistency that -- or at least I would have challenged the group's consensus on that. I mean, don't you want to include those people?

DR. KAUFMAN: So the Category 1 is a fee for three months of care.

DR. BERENSON: Yeah.

DR. KAUFMAN: And if the diagnosis is made and it doesn't fall into a category that requires that three months of care and it is not a primary headache disorder, it didn't seem right to include

that patient.

DR. BERENSON: Yeah. Okay.

DR. KAUFMAN: It would seem to Medicare the most cost-effective thing to do is to pay that E&M consult fee, and then the patient moves on rather than --

DR. BERENSON: So then, this does really seem to be a proposal for managing migraine and cluster headaches is what it seems like, despite your letter response.

DR. KAUFMAN: Well, it's not just migraine and cluster. I mean, it's tension headaches. It's medication overuse headaches. It's --

DR. BERENSON: So they would fall into those ICD-10 categories as in the appendix?

DR. KAUFMAN: Yes.

DR. BERENSON: Okay. But not when there's another primary -- okay. So some are included -- I think it would be very helpful if you guys -- if you wrote that up and talked more specifically about what headaches -- not just the list, because we don't understand what's included under each of those ICD-10 -- so I missed -- you know, I think it would be useful for you to provide a supplementary

letter, which went through all of these other kinds of headaches. And explain which ones would be included and which one -- and which ICD-10 code would we be looking for and which ones would not be included, even though the referral would have taken place and care was being provided -- or diagnostic decision-making was happening. And I think that would be very helpful for our review.

DR. KAUFMAN: We thank you for that suggestion, yeah.

I apologize for the -- not including the comorbidities.

DR. BERENSON: Yeah. I mean, so what we want to do is get a sense, and we have -- in addition to what you're doing, we have sources to provide some data for us, and we'd want to look at sort of the prevalence and costs, if we can, associated with what you're proposing to decide if it should be a high-priority alternative payment model, and so to have a better sense of the universe of patients that would be included would be very helpful.

DR. KAUFMAN: Yes.

DR. BERENSON: And then it also is

relevant to -- you know, we were asking you questions about how common is it for migraine to be either undiagnosed or misdiagnosed in a Medicare population. I think a little more information for just the conditions that you would include in the model for how much -- how big a Medicare problem this is.

Obviously, your example of medication overuse headaches in a Medicare population is relevant, quite relevant, and any references to prevalence, et cetera, would be very helpful.

But if, in fact, temporal arteritis and cervical arthritis and some other conditions are not included, then we would need to know that too. So, a little more specificity on what's in and what's out and what codes.

And so, one additional question there that Kavita was getting at, which I just want to ask again -- So the trigger for the payment is one of those ICD-10 codes showing up on a claim? Is that right? And then somehow an opt-in -- and somehow the patient has to opt in. And that might be some questions we'll take up on another call, you know, how that would work. But is the trigger sort of

the formal opt-in by the patient, or is it simply the diagnosis that shows up on a claim?

DR. KAUFMAN: Both.

DR. BERENSON: Both.

DR. KAUFMAN: And I'm -- and let me turn to both Amandas. I'm not a proud person, so I would turn to them. If I've said anything incorrectly, now is the time to speak up and correct me, and please do so at any point.

MS. NAPOLES: This is Amanda Napoles. I have nothing to correct. That's right. We've talked about having both the ICD-10 code and the patient opt-in be the trigger for the payment model.

MS. BECKER: And this is Amanda Becker. I agree.

DR. BERENSON: So let me just then take the -- since we do have a few more minutes -- the opt-in.

So presumably, I'm a patient who’s opted in, but I'm seeing my primary care physician for a whole range of my other problems. Do you have any expectations about I'm having what I think might be a drug side effect or something like that, that

physician is going to -- do I tell my primary care physician about that? What happens? Does that physician sort of have to contact the headache center to say, "This patient is complaining of something, and I'm seeing them. What do you want me to do?" or do they manage it? I mean, have you thought about any problems associated with that?

DR. KAUFMAN: Yes, we have.

And unfortunately, that's not infrequent now, particularly in elderly patients --

DR. BERENSON: Right.

DR. KAUFMAN: -- because often one of the first-line drugs used would be low-dose amitriptyline, and again, in the elderly, there can be significant discomfort, side effects, anticholinergic effects.

DR. BERENSON: Right.

DR. KAUFMAN: So part of what the extra payments will cover is the coordinator, or someone from the office, who will keep in contact with the patient. So it's not a surprise to anyone that the patient is having difficulty with the medication or --

DR. BERENSON: I see.

DR. KAUFMAN: -- some side effects.

That's something that's not covered now. So part of that first three months is someone that keeps in contact with that patient proactively, and then for patients that are well-controlled in our Category 3, there's communication, there's someone who's monitoring, there's access to the neurologist -- either it's a real team or virtual team, but coordination of care, patient-centered -- avoiding surprises is one thing we're really aiming for in our model.

So thank you for asking that question. It's an important one, and it's one that we were really focused on.

DR. BERENSON: Okay. So if possible, if I'm the primary care physician, you'd actually want me to tell the patient to call their APP, who they know very well, and report it to them and not have me fool around with their medication?

DR. KAUFMAN: Well, hopefully, in our model, the patient will say someone from the -- from -- the coordinator has been in contact with me. They already know that I'm having the side effects.

DR. BERENSON: Oh, okay. Yep. Okay.

DR. KAUFMAN: They've already communicated --

DR. BERENSON: Fair enough.

DR. KAUFMAN: -- electronically or otherwise to the primary care physician. Our mutual patient is having this issue. We're on top of it.

DR. BERENSON: Okay, got it.

DR. KAUFMAN: That's the whole idea here, because --

DR. BERENSON: Got it.

DR. KAUFMAN: -- compliance with prophylactic medication is -- or any medication, chronic medication, is a real issue, which leads to patients being difficult to control. So, we -- one of the essence -- pieces -- piece of our model is to have a proactive program to recognize that.

DR. BERENSON: Yep, okay. Okay. Let's sort of wind down.

I think it turns out that we have another call amongst ourselves on Friday of this week. So rather than you going back right now to do what I suggested, why don't you wait to hear from us,

either close of business Friday or on Monday, with our suggestions for what additional information we would want to clarify where there's been some misunderstanding, whether we want you to do sort of a modest revision of the proposal, or whether we simply want a supplemental letter which clarifies some of these things? We will want to send back to you some guidance on that, and since we're meeting in two days, there's no reason for you to rush and get us a response. So we'll be back to you, now that we have a much better understanding of what your objectives are.

And, I mean, just parenthetically, I was actually on the Institute of Medicine Committee on Diagnosis Accuracy and have -- and I'm quite interested in the topic of payment models that support more accurate diagnosis. I think that's a problem that has been lost in all of the value-based payment conservations. They always assume an accurate diagnosis, and so I'm very interested in trying to figure out how this could work as a prototype of that.

And so at least for me -- I'll speak for myself -- I'm sympathetic to the problem you've

defined and approach to trying to deal with it. Whether this payment -- I mean, whether the model right now is going to work or not, where you still have to discuss, but -- so I'm not -- I mean, I'm sympathetic to your objectives.

DR. KAUFMAN: Thank you.

DR. BERENSON: In fact, I'm personally a little disappointed that the focus seems to be a little less on getting the diagnosis right than on the management of the patients.

DR. KAUFMAN: Right.

DR. BERENSON: So I probably, if I were on your committee, would have voted differently, but we'll see. We'll see.

DR. KAUFMAN: Well, we didn't -- well, we wanted to just be careful of that first phase.

I look forward to presenting our epilepsy APM. We have two of them. We have this, and we have the epilepsy. We decided to go with this one first because it's a little simpler model. Our epilepsy has nine categories, but about a third of patients referred to neurologists now have non-electrical seizures, and so there, the diagnosis issue is the biggie --

DR. BERENSON: I see.

DR. KAUFMAN: -- Even more than this one.

Would it be helpful, even before Friday, for us to forward to you the comorbidity list?

DR. BERENSON: That would be absolutely helpful. Yes. That, you should do. If you have such a list and don't have to pull it together, then by all means send it to us.

DR. KAUFMAN: Yeah. No, we have -- we definitely have the list, and --

DR. BERENSON: Okay. That would be very helpful. It would be in the long term -- I mean, I guess I'll speak out of school here. It's more difficult to conceive of having a payment model for each condition that needs to be better diagnosed than to have a generic model that epilepsy and headaches could fit into somehow.

DR. KAUFMAN: Right.

DR. BERENSON: I mean, that's the challenge of -- do we want a thousand payment models for each condition that could benefit, or can we figure out a generic approach --

DR. KAUFMAN: Right.

DR. BERENSON: -- that would handle -- I

mean, has your committee sort of thought through that -- whether there's enough commonality in epilepsy and headaches that you could come up with sort of a generic approach to diagnosis?

DR. KAUFMAN: Our generic model is initial evaluation and treatment, and then the fork in the road, the patient doing well, not doing well.

DR. BERENSON: I see.

DR. KAUFMAN: So that's our -- that's our generic path.

I agree with you on -- I have this discussion. It's a death-by-a-thousand-cuts if you have so many of these APMs, and I think the difficulty is patients that may not -- you know, the half of patients that don't fit into any chronic care -- care model.

DR. BERENSON: Right.

DR. KAUFMAN: So how do you have something that's workable, scalable, but not so overly finite that it's worse than the current system now?

DR. BERENSON: Right. Or we vulcanize all care. We vulcanize care into these categories.

But we're taking up our time. I think we've had a -- anything else, the PRT or ASPE

folks? Anything else you guys want to ask, or anybody else from AAN who has anything to add to this very good conversation?

DR. MEDOWS: Thank you for taking the time this morning.

DR. BERENSON: By all means, send us that list, and then we will give you some guidance after we meet again on Friday about where we are.

MS. STAHLMAN: Bob, this is Mary Ellen.

DR. BERENSON: Yep.

MS. STAHLMAN: One thing I'd mention to the submitter is you might, between now and when you receive that guidance, just familiarize yourself with the option that you have to withdraw and then revise and then resubmit your proposal at any time. So we've talked about a lot of things that have clarified your proposal, and as Bob mentioned, that might come in written guidance from the PRT to you in further questions.

Another option for you is to sort of integrate it all into your proposal and then resubmit it so that it's all in one place. The appendix is there, you've clarified or corrected the $4,000 figure, you've done some of these things

that we've talked about, so that when this proposal does go to the full PTAC for public deliberation, all of the material is in one place.

So it's an option that's available. If you do revise the proposal and resubmit it, it would be given to the same PRT that you met with this morning, and it just might be one option for you to consider.

DR. KAUFMAN: Does that delay the presentation to the full committee?

MS. STAHLMAN: Well, it puts it all in one place, and so, yes, it will likely push it out another meeting. On the other hand, because the same PRT would be looking at the proposal and because they would have great familiarity with it, there isn't the same learning curve, and we probably wouldn't be asking for -- they wouldn't be asking the staff for the same level of analysis on the proposal, so it does speed it up a little bit. But it would likely push it out one more meeting. And I think you have to ask yourself, "Oh, but is it worth it? Because if I'm dealing with 11 experts on the PTAC, do I want it in one place so that they are not going to various documents and

having to assimilate it themselves?" -- versus you doing it for them.

The Chair said to another submitter at one point who did decide to revise and resubmit, “You want to present your best work to the full Committee, so that they're able to get their arms around it.”

So -- and I'm not sure that we're at that point yet. I think that's what Bob is alluding to -- He's going to come back -- the PRT will come back to you with some more questions. And, I just wanted you to have in the back of your head and to have read the submitter instructions online, which has a little section that just mentions your --

DR. KAUFMAN: Right.

DR. BERENSON: And let me just say I think that's a very good thing. I'm glad you brought that up. That in the end, what the PTAC will be reviewing is your original proposal, and although the PRT can explain that, well, there were some -- in our back-and-forth -- and all of that will be available -- there were some clarifications or even modifications -- that actual proposal is what people will be reviewing fundamentally. And so, I

again -- if it didn't capture what you were trying to accomplish, you might think of -- it would not be a full -- we wouldn't be starting as -- as Mary Ellen said, it would probably be just a one-meeting delay. It wouldn't -- you wouldn't be starting back at the beginning, not "Passing Go," or whatever the Monopoly line is, "Get out of Jail Free." So --

MS. BECKER: This is Amanda Becker.

Can I just ask are we currently talking on track for March? So we're talking about delaying to June, or is that not even set for sure?

MS. STAHLMAN: The March agenda is not set yet. So it just depends --

MS. BECKER: Okay.

MS. STAHLMAN: We need -- we -- the PRT will put their report about whatever March proposals there are on the website at the very beginning of March. They do it three weeks prior to the meeting, and so all of their fact finding needs to be wrapped up. And then they have to write a report, and three busy people have to review it and all of that. And then it needs to be -- the material needs to be published.

So it's not clear yet which proposals will be at that point for March versus June.

MS. BECKER: Got it.

DR. BERENSON: But it is possible, not necessarily likely, but quite possible that if you did a quick revision and resubmit, you could be on for June.

DR. KAUFMAN: All right. Yeah, we'll -- our goal is to get this approved, and neurologists, we try to be good listeners. So we appreciate the recommendation and --

DR. BERENSON: No recommendations. No recommendations. Just --

DR. KAUFMAN: Well, in terms of how to proceed, but --

DR. BERENSON: Yeah. Just something for you to think about.

DR. KAUFMAN: Right.

DR. BERENSON: We're not giving you any directives. Let's put it that way. It's your decision, but I just wanted to clarify that. We're not allowed to give you technical assistance either, but --

DR. KAUFMAN: All right.

DR. BERENSON: It's just part of our mandate.

DR. KAUFMAN: Sorry. We appreciate it.

DR. BERENSON: But that's okay.

Okay. But we will, after we meet, give you any -- we'll give you some guidance after we meet again on Friday.

DR. KAUFMAN: We appreciate that very much, and thank you all for your time and your review. It's kind of neat. Thank you.

DR. BERENSON: Okay. I think --

DR. SAMSON: Thank you very much.

DR. BERENSON: I think we're done.

MS. STAHLMAN: Have a good day, everybody.

DR. KAUFMAN: Thank you. Bye.

MS. NAPOLES: Thank you. Bye.

DR. BERENSON: Thank you.

[Whereupon, at 11:01 a.m., the conference call concluded.]