CALIFORNIA TECHNOLOGY ASSESSMENT FORUM℠

An Action Guide for the Treatment of Migraine: Payers and Policymakers

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ICER
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Introduction

About This Guide

Evidence from clinical research, which informs effectiveness reviews, provides a critical foundation for judgments that patients, clinicians, and health insurers must make about treatment choices and coverage policies. Yet that evidence is often not translated in a way that is helpful to inform health care decisions. This document is a companion action guide designed to help payers and policymakers make use of the results of a recent technology assessment entitled "*Controversies in Migraine Management*" developed by the Institute for Clinical and Economic Review (ICER) and faculty at University of California, San Francisco. This report formed the basis for the deliberations and votes of the California Technology Assessment Forum (CTAF) Panel – an independent committee of medical evidence experts from across California, with a mix of practicing clinicians, methodologists, and leaders in patient engagement and advocacy, who evaluate evidence and vote on the comparative clinical effectiveness and value of medical interventions. All CTAF Panel members meet strict conflict of interest policies.

CTAF held its public meeting on controversies in migraine management on July 11, 2014 in Los Angeles, California. A full report summarizing the discussion and votes taken is available on the CTAF website. We have developed this Action Guide to provide a list of specific evidence-based action steps that payers and policymakers can take to improve patient outcomes and the overall value of treating migraine. This guide serves as a companion to the evidence review and meeting results. The content provided here is for informational purposes only, and it is not designed to replace professional medical advice.

A Note on CTAF Evidence Voting

Each public meeting of CTAF involves deliberation and voting on key questions on the comparative clinical effectiveness and value of the various diagnosis and treatment options discussed. When voting, CTAF Panel members are not provided with prescribed thresholds or boundaries for how to interpret value. Rather, the CTAF Panel members are asked to assume the perspective of a state Medicaid program or a provider organization making resource allocation decisions within a relatively fixed budget.

Action Steps for Payers and Policymakers

The following action steps are designed to help payers and policymakers encourage appropriate treatments for patients with migraine.

1. Health plans may wish to consider adding more choices within a drug class.

Clinical understanding of the causes and classifications (episodic vs. chronic, with or without aura) of migraine is evolving, and, as such, it is difficult for clinicians to know which treatment will be the most effective for a patient given a specific set of symptoms. Insurers should consider broadening available treatments for migraine by adding more choices within a particular drug class (e.g., triptans). It is important for clinicians to be able to try and retry a variety of preventive and abortive agents, as this may increase the likelihood of identifying effective treatment(s) and improving patient outcomes.

2. Step therapy requirements prior to BOTOX authorization are reasonable, as are stopping rules if there is no response to treatment.

Clinicians on the CTAF Policy Roundtable[1] noted that the effectiveness of BOTOX can vary widely from patient to patient, and that there is no way to predict patient response. These issues, combined with the presence of a large placebo effect in clinical trials, provide support to step therapy and stopping rules for the use of BOTOX. Many private payers currently require step therapy before approving BOTOX for the prevention of chronic migraine, but public payers including Medicare and Medi-Cal do not have these requirements.

BOTOX Coverage Policies

Medicare & Medicaid

Medicare/Noridian: http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33513&ContrId=280&ver=9&ContrVer=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=California+Entire+State&KeyWord=botulinum+toxin&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAAAAAAAA%3d%3d&

Medi-Cal: http://files.medi-cal.ca.gov/pubsdoco/bulletins/artfull/ph201105.asp#a10

[1] The Policy Roundtable at the July 11, 2014 CTAF meeting was composed of neurologists and headache specialists, a patient advocate, and payer representatives, all of whom were asked at the meeting to disclose any conflicts of interest.

Health Net:
https://www.healthnet.com/static/general/unprotected/html/national/pa_guidelines/xeomin_natl.html

Aetna:
http://www.aetna.com/cpb/medical/data/100_199/0113.html
http://www.aetna.com/products/rxnonmedicare/data/2014/MISC/botulinum_toxin.html

Anthem/WellPoint:
http://www.anthem.com/medicalpolicies/policies/mp_pw_a049843.htm

Cigna:
https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/pharmacy/ph_1106_coveragepositioncriteria_botulinum_therapy.pdf

Humana:
http://apps.humana.com/tad/tad_new/Search.aspx?criteria=botox&searchtype=freetext&policyType=both

United Healthcare:
https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20Policies/Drug%20Policies/Botulinum_toxin_policy.pdf

3. **Insurers should partner with clinicians, purchasers, and other policymakers to implement quality improvement initiatives to reduce opioid prescribing for migraine pain.**

Nationally, 53% of patients seeking relief from migraine pain in the ED receive opioids, despite strong clinical evidence showing that opioids are not the most effective treatment. Efforts to reduce rates of opioid prescribing in the ED for migraine relief may result in improved patient outcomes and large cost savings. Health plans should participate in quality improvement initiatives that involve measurement and reporting of results, with a goal of reducing the use of opioids in the ED. Congruence between patient treatment plans and the actual treatments rendered might be used as a quality improvement metric for EDs.

4. **Specialty societies should work collaboratively on a campaign to reduce the use of opioids to treat migraine pain in the emergency department (ED).**

Even though specialty guidelines discourage the use of opioids for migraine pain relief, an educational campaign is needed to change the behaviors of both clinicians and patients and should discuss alternative treatments as well as the potential harms of opioid use for migraine pain relief. While some patients will need opioids to relieve migraine pain, they should be used as a last resort. Opioids carry risks of dependence and misuse, as well as a greater risk of transforming migraines from episodic to chronic compared to triptans, NSAIDs, and acetaminophen. As noted previously, strong clinical evidence suggests that opioids are not the most effective treatment. Rather, the most effective treatment is combination therapy of dihydroergotamine (DHE) along with either neuroleptics or metoclopramide, or neuroleptic monotherapy. Alternatives that are equally effective as opioids include metoclopramide monotherapy and NSAIDs.

Current guidelines related to migraine are available here:

American Academy of Neurology (AAN)
https://www.aan.com/Guidelines/Home/ByTopic?topicId=16
http://www.choosingwisely.org/doctor-patient-lists/american-academy-of-neurology/
http://www.neurology.org/content/78/17/1337.full.html

American Headache Society (AHS)
http://www.americanheadachesociety.org/assets/1/7/How_I_Do_It_Acute_Treatment.pdf
http://www.americanheadachesociety.org/new_guidelines_treatments_can_help_prevent_migraine/
http://www.choosingwisely.org/doctor-patient-lists/american-headache-society/

American Academy of Family Physicians (AAFP) / American College of Physicians (ACP) / American Society of Internal Medicine (ASIM) Joint Guideline
http://annals.org/data/Journals/AIM/20020/0000605-200211190-00014.pdf

Canadian Headache Society / Canadian Journal of Neurological Sciences (CJNS)
http://headachenetwork.ca/wp-content/uploads/Acute-migraine-guideline.pdf
http://headachenetwork.ca/wp-content/uploads/CanadianHeadacheSocietyGuidelineforMigraineProphylaxis.pdf

British Association for the Study of Headache (BASH)
http://www.bash.org.uk/wp-content/uploads/2012/07/10102-BASH-Guidelines-update-2_v5-1-indd.pdf

More information may be found at these links (and in the Appendix):

- San Diego County Medical Society:
  http://www.sandiegosafeprescribing.org/

http://www.sdcms.org/Portals/18/Assets/Lev%20Docs/SafePrescribingEnglish91113Cropped.pdf (English)
http://www.sdcms.org/Portals/18/Assets/Lev%20Docs/SafePrescribingSpanishCropped.pdf (Spanish)

- National Institutes of Health: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3663475/pdf/ndt-9-709.pdf

5. Licensing organizations should review the evidence on opioid use to treat migraine pain and revise guidelines to reflect current evidence.

In the Policy Roundtable discussion, it was noted that over the past 20 years, the Medical Board of California established guidelines to improve prescribing practices for effective pain management. The guidelines encouraged clinicians to "view effective pain management as a high priority in all patients" and were designed so that "physicians have a higher level of comfort in using controlled substances, including opioids, in the treatment of pain." It was suggested during the policy roundtable discussion that a perception of providers under-treating pain led to the development of guidelines that created an unintended consequence of over-treating pain with opioids, particularly in the ED. These guidelines should be reviewed and updated to reflect current evidence.

Sources of current guidelines are listed in recommendation #4 above.

6. Invest in further basic science research and research on the effectiveness of various migraine therapies.

Clinical understanding of the basis for migraine is evolving, and there have been recent advances in the understanding of causal factors and migraine triggers, as well as in the definitions of types of migraine (episodic and chronic). Yet, more research is needed to answer the many questions that remain about the exact causes and specific classification of migraines. Without these answers, it is particularly challenging for clinicians to make accurate and precise diagnoses and to identify effective treatments.

In addition, more high-quality, large research studies are needed to examine the effectiveness of various migraine therapies. Despite the challenges the placebo and nocebo effects present to the development of high-quality studies on the Cefaly and SpringTMS devices and BOTOX, these studies, as well as RCTs directly comparing BOTOX to oral agents for chronic migraine prevention, are needed to identify the most effective treatments available. Non-industry funded studies in particular would produce the most compelling evidence.

APPENDIX

SAFE PAIN MEDICINE PRESCRIBING
IN EMERGENCY DEPARTMENTS

We care about you. Our goal is to treat your medical conditions, including pain, effectively, safely and in the right way.

Pain relief treatment can be complicated. Mistakes or abuse of pain medicine can cause serious health problems and death.

Our emergency department will only provide pain relief options that are safe and correct.

For your SAFETY, we follow these rules when helping you with your pain.

1. We look for and treat emergencies. We use our best judgment when treating pain. These recommendations follow legal and ethical advice.
2. You should have only ONE provider and ONE pharmacy helping you with pain. We do not usually prescribe pain medication if you already receive pain medicine from another health care provider.
3. If pain prescriptions are needed for pain, we will only give you a limited amount.
4. We do not refill stolen prescriptions. We do not refill lost prescriptions. If your prescription is stolen, please contact the police.
5. We do not prescribe long acting pain medicines such as: OxyContin, MSContin, Fentanyl (Duragesic), Methadone, Opana ER, Exalgo, and others.
6. We do not provide missed doses of Subutex, Suboxone, or Methadone.
7. We do not usually give shots for flare-ups of chronic pain. Medicines taken by mouth may be offered instead.
8. Health care laws, including HIPAA, allow us to ask for all of your medical records. These laws allow us to share information with other health providers who are treating you.
9. We may ask you to show a photo ID when you receive a prescription for pain medicines.
10. We use the California Prescription Drug Monitoring Program called CURES. This statewide computer system tracks opioid pain medications and other controlled substance prescriptions.

If you need help, please call 2-1-1 and ask for information on treatment services for drug use disorders.

Emergency Departments throughout Los Angeles County have agreed to participate in this important program.

To discuss safer and more helpful chronic pain treatment options, please schedule an appointment with your treating physician.

County of Los Angeles Public Health

Health Services Los Angeles County

California ACEP American College of Emergency Physicians

Los Angeles County Medical Association

Hospital Association of Southern California

Kaiser Permanente

ADMINISTRACIÓN DE MEDICAMENTOS PARA EL DOLOR

EN LA SALA DE EMERGENCIAS

Nos preocupamos por su salud y bienestar y por lo mismo, nuestro objetivo es tratar sus condiciones médicas—incluyendo el dolor que sienta—de una manera eficaz, segura y adecuada.

El tratamiento para aliviar el dolor puede ser complicado. Los errores o el abuso de medicamentos con receta para lidiar con el dolor pueden provocar graves problemas de salud y hasta la muerte.

Nuestro departamento de emergencias le proporcionará únicamente opciones de alivio del dolor que sean seguras y adecuadas.

Por su salud, siempre que le brindemos ayuda para lidiar con su dolor, seguiremos estas medidas de seguridad:

1. Determinamos y tratamos emergencias. Usamos nuestro mejor criterio para tratar el dolor. Estas recomendaciones siguen consejos legales y éticos.
2. Nos aseguramos que tenga UN solo proveedor y UNA sola farmacia que le ayuden con su dolor. Normalmente no le recetaremos medicamentos para el dolor si usted ya recibe un medicamento contra el dolor de otro proveedor médico.
3. Si necesita un medicamento recetado para lidiar con su dolor, le daremos una cantidad limitada.
4. No surtimos recetas que fueron robadas ni recetas perdidas. Si le roban su receta de un medicamento contra el dolor, por favor póngase en contacto con su proveedor médico, la policía o el sheriff.
5. No recetamos medicinas para el dolor crónico como: OxyContin, MSContin, Fentanyl (Duragesic), Metadona, Opana ER, Exalgo entre otros.
6. No surtimos dosis perdidas de Subutex, Suboxona ni de Metadona.
7. No solemos proveer inyecciones de alivio rápido para el dolor crónico agudo. De intensificarse el dolor, es posible que se le ofrezca un medicamento oral.
8. Las leyes de protección a la salud, entre ellas HIPAA, nos dan acceso a su expediente médico. Estas leyes nos permiten compartir información con otros proveedores médicos que le brindan atención médica.
9. Podemos pedirle que nos muestre una identificación con fotografía cuando reciba un medicamento recetado para el dolor.
10. Usamos el programa *Controlled Substance Utilization Review and Evaluation System* (CURES en inglés), un sistema electrónico estatal que nos permite tener precaución y monitorear la frecuencia con la cual se receta un medicamento opioide para el dolor entre otras sustancias controladas.

Si necesita ayuda, por favor llame al 211 y pida información sobre los servicios de tratamiento para los trastornos por consumo de drogas.

Todos los departamentos de emergencia del Condado de Los Ángeles han aceptado participar en este importante programa.

Si desea aprender más sobre sus opciones para lidiar con el dolor crónico de una manera más segura y eficaz, hable con su médico de cabecera acerca de los tratamientos disponibles.

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