AMCP Webinar: Market Insights – Future Treatments in Migraine and Cluster Headaches

April 2, 2020

From AMCP Nexus 2019

AMCP

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Improving lives.

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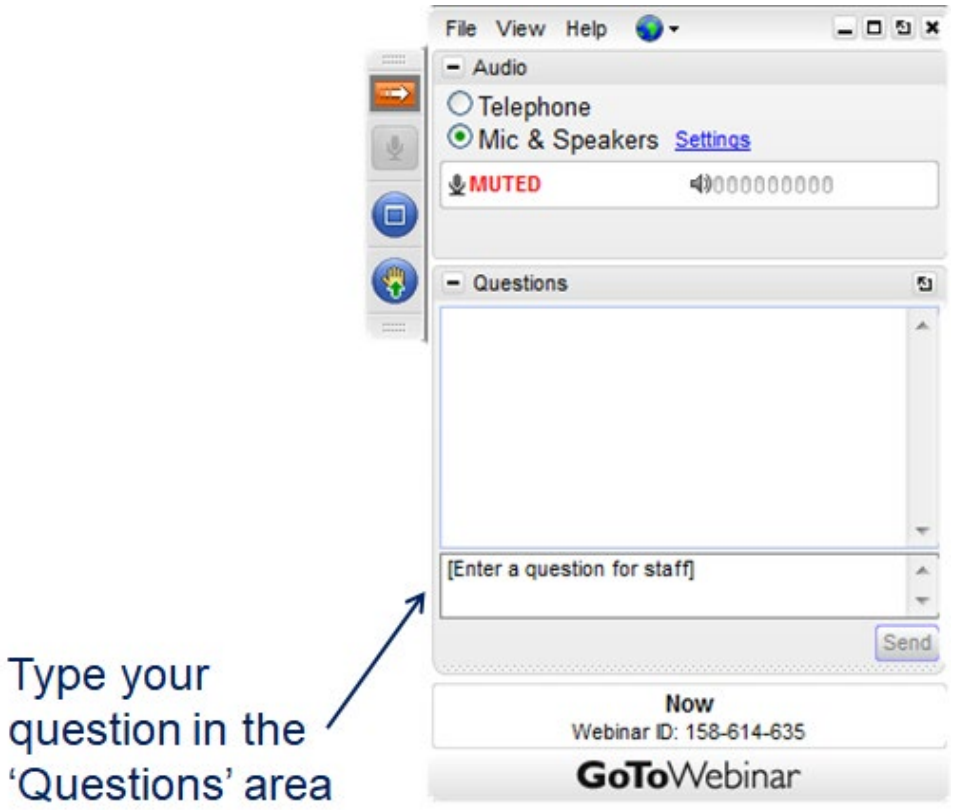

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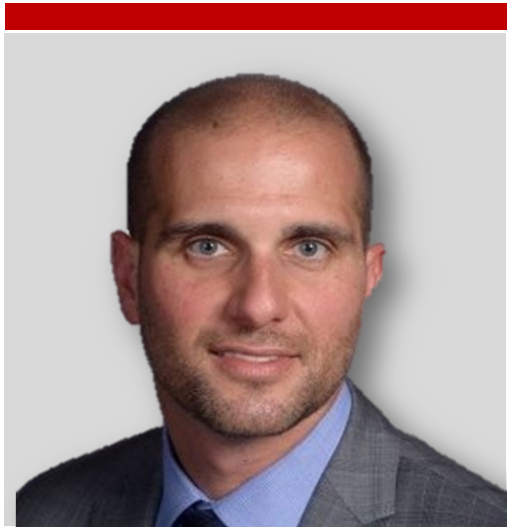
MARKET insights RESEARCH



Welcome
Matt Lowe, Vice President,
Business Strategies.
AMCP

Moderator and Presenter
Destin Sampson, PharmD, MBA
Managing Director
VEO Market Access

AMCP

AMCP Market Insights Overview

- **Association-led research** with AMCP members and non-members at regional and national plans
- **Blinded format** to allow participation and candid feedback
- **Topics are based upon category**, not product, to provide a holistic view of management
- Programs are **focus group meetings or virtual programs** with Clinical Key Opinion leader presentation
- **Current and future treatment options** are addressed to understand clinical and medical management utilization approaches

Migraine Market Insights

AMCP Nexus 2019 Moderator and Presenter:
Destin Sampson, PharmD, MBA
Managing Director
VEO Market Access

Agenda

Guest Speaker:

Jessica Ailani M.D. FAHS

- Director, Medstar Georgetown Headache Center
- Associate Professor Neurology
- Medstar Georgetown University Hospital

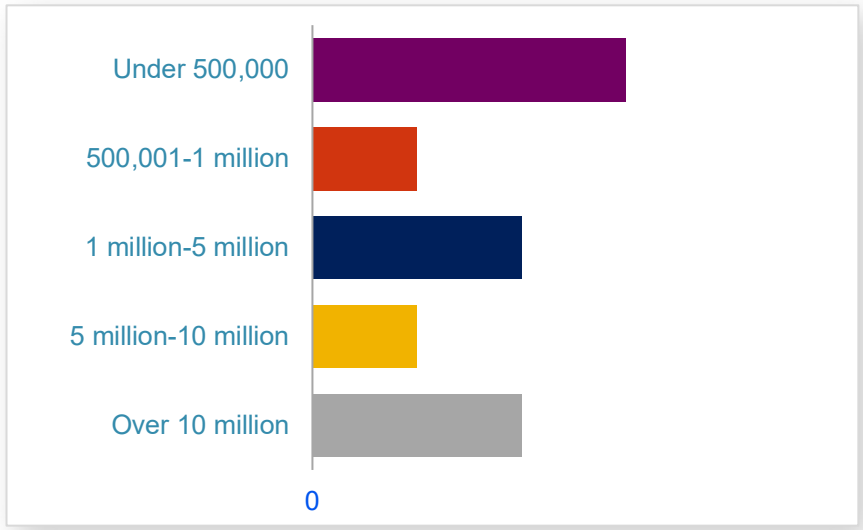
Time	Session Title
7:30 AM – 8:00 AM	*Breakfast*
8:00 AM – 8:45 AM	**Welcome & Setting the Stage for the Day**
8:45 AM – 10:00 AM	**Migraine Management- Laying the Foundation Acute Management** Presenter: Jessica Ailani, MD
10:00 AM – 10:15 AM	*Break*
10:15 AM – 12:00	**Migraine Management – Laying the Foundation Preventative Management** Presenter: Jessica Ailani, MD
12:00 PM – 12:30 PM	*Lunch*
12:30 PM – 1:30 PM	**Cluster Headache- Differentiation & Management Approaches** Presenter: Jessica Ailani, MD
1:30 PM – 2:00	**Putting it all together – Group Discussion**
2:00 PM – 2:15 PM	*Break*
2:15 PM – 2:45 PM	**Workshop 1:**
2:45 PM – 3:00 PM	**Wrap-up and Closing Remarks**

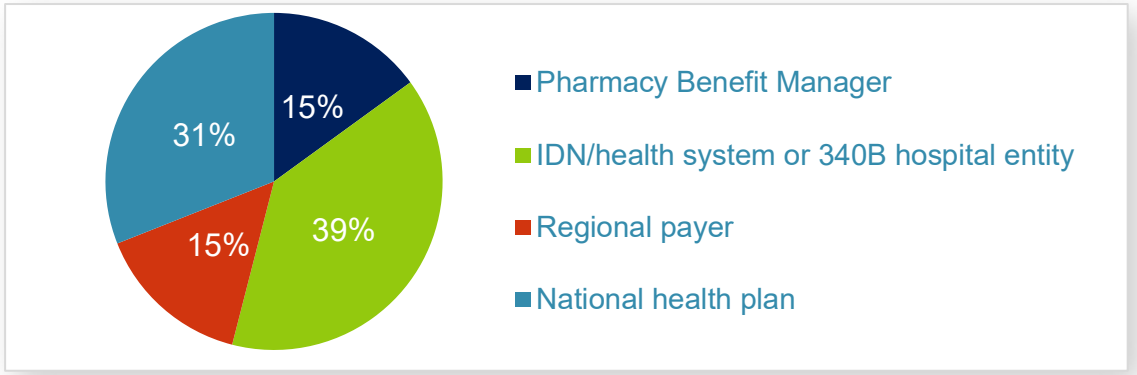
Objectives

- Understand how AMCP members identify and manage members with migraine and cluster headaches
- Identify how payers establish coverage criteria for new migraine therapies
- Define key information required for payers to aid product differentiation, treatment protocols, and utilization review to ensure optimal outcomes for members
- Understand types of RWE needed for use in formulary decision-making and gaps in currently available data
- Define the role of non-pharmaceutical treatment options in patient management

Methodology

- 6-hour live meeting on November 1 at 2019 AMCP NEXUS
- Roundtable format, with presentations and group discussion
- > 30 million lives covered





National and regional plans as well as broad range of PBMs- national and regional..

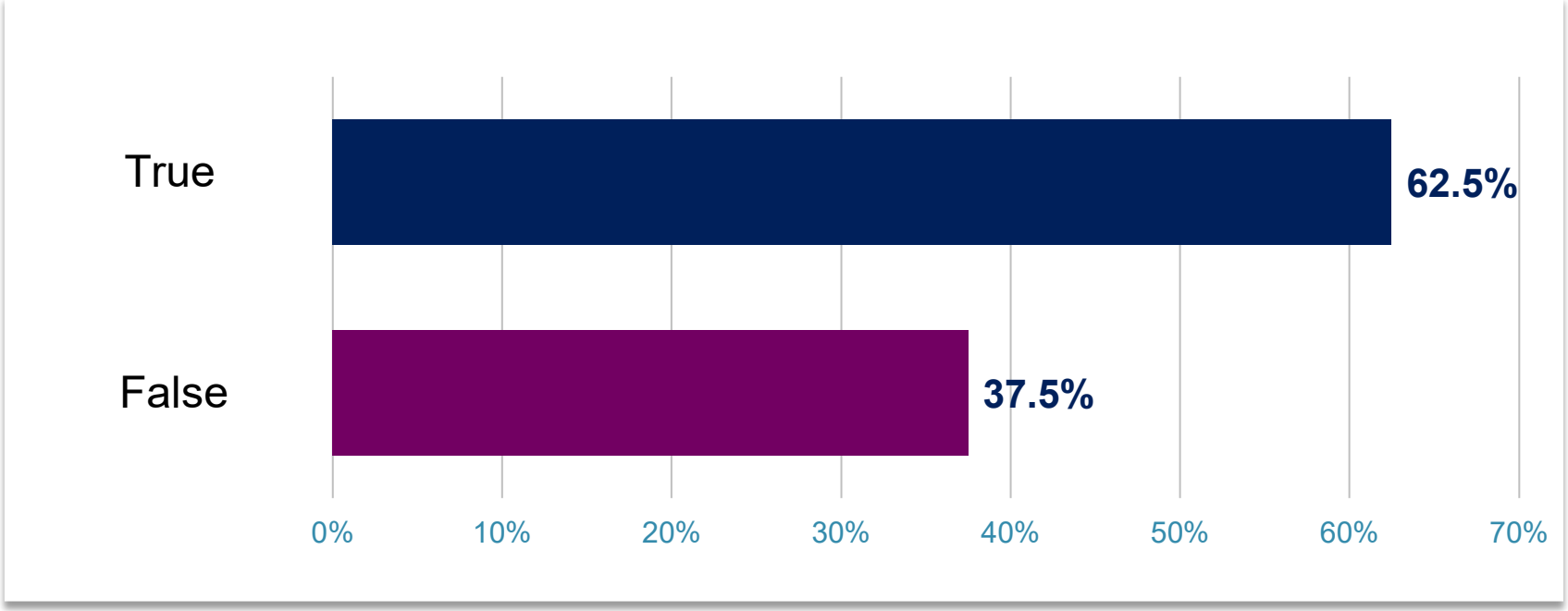
Meeting Overview

- Setting the Stage: Premeeting Survey Results
- Clinical Overview: Defining Migraine and Cluster Headaches
- Clinical Overview: Laying the Foundation for Episodic Treatments
- Migraine Management: Laying the Foundation for Preventive Management
- Cluster Headache: Differentiation and Management Approaches

Executive Summary

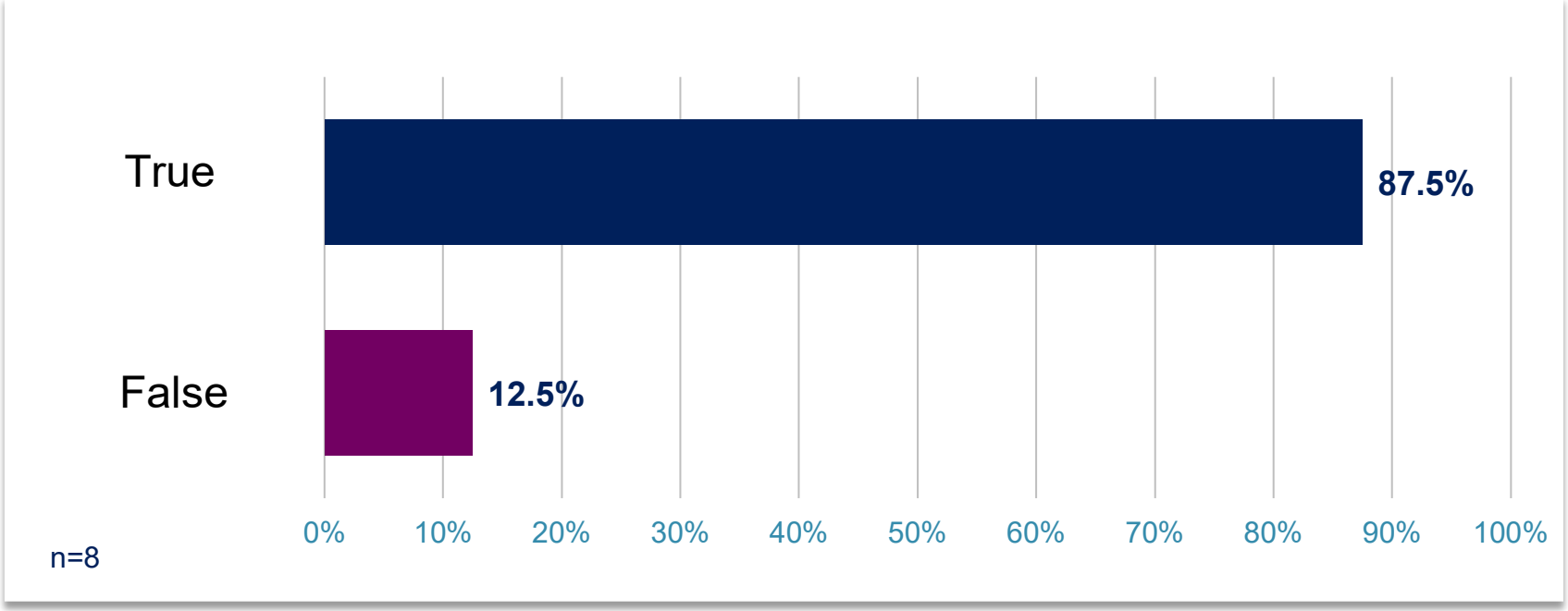
Most participants perceived the need to fail more than one triptan to gain access to the CGRP class

Failing one triptan is a reasonable step edit before allowing coverage for a CGRP monoclonal antibody antagonist to treat cluster headache disease.



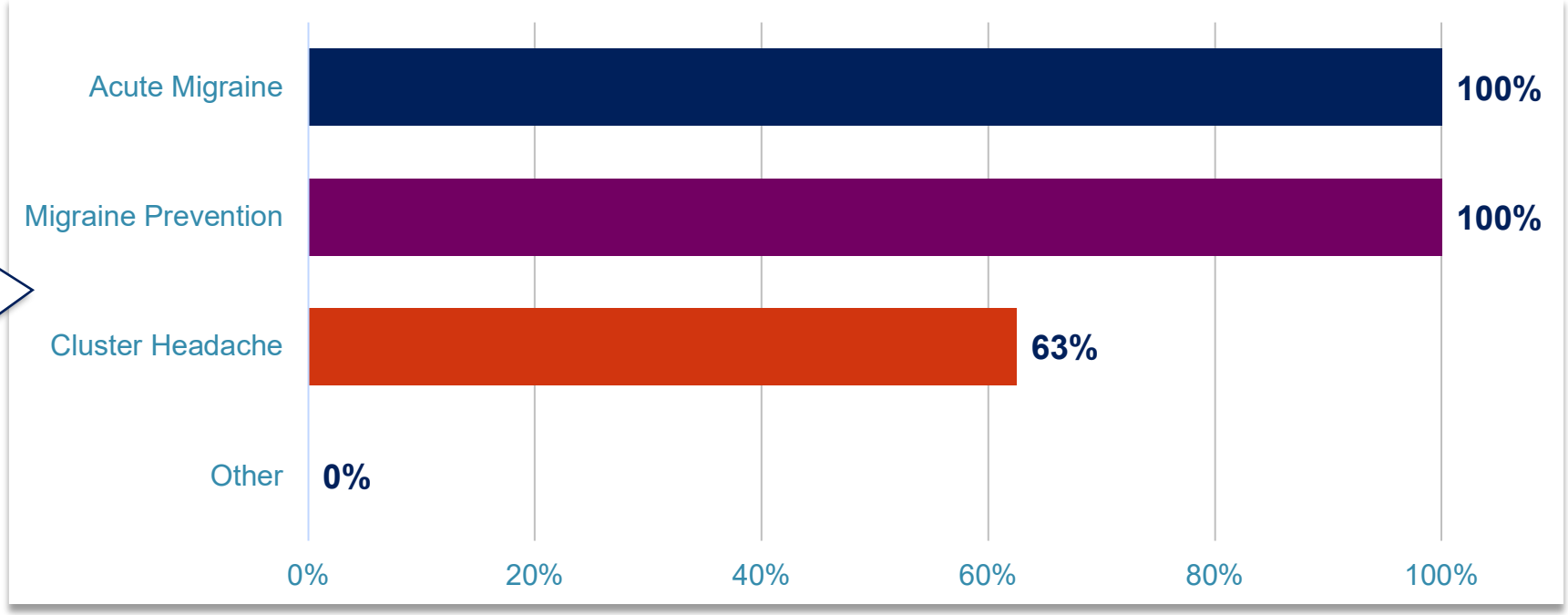
Almost all participants were aware of the lack of response to triptan therapy in patients

About 30–40% of people with migraine do not respond adequately to triptan therapy.



Prior to meeting, just over half of participants considered cluster headaches in the migraine category

In defining the migraine category for formulary, which types of headache diagnosis are included: (select all that apply)



"I think generally they all kind of fit together management-wise"
– Health Plan

General Meeting Overview

Improved education of migraine and cluster headache altered the participants' perception of the condition and the therapies

Single Market Basket

"They fit together"

Migraine
(acute, preventative, cluster headache)

Treat the Episode

- Treatment is generally considered a cure for the episode
- Cluster may be a more severe migraine or severe derivative of migraine

Definitions/Guidelines
Clinical Education
Provider Practices

Distinct Categories

Episodic Migraine

Chronic Migraine

Cluster Headache

Cure vs Chronic

- Migraine in some patients may be a chronic disease and treated appropriately
- Cluster headache is a separate condition with severe episodes

"[migraine is chronic,] I think I already knew that, but I don't think I've ever heard that"
- Health Plan

Recently Approved CGRPs & Novel Mechanism

	Acute / Episodic	Prevention	Cluster Headache	Oral	SQ	IV
erenumab (Aimovig)		X			X	
galcanezumag (Emgality)		X	X		X	
fremanezumab (Ajovy)		X			X	
Recently approved since AMCP Market Insights Meeting						
eptinezumab (Vyepti)	X	X				X
lasmiditan (Reyvow)	X			X		
rimegepant Nurtec ODT	X			X		

Episodic and Chronic Migraine

Definitions for Episodic Migraine and Treatment Recommendations

Migraine

Without Aura:

At least five attacks

Attacks last 4-72 hours untreated

At least 2 of the following 4 characteristics

- Unilateral location
- Pulsating quality
- Moderate or severe pain intensity
- Aggravation by or causing avoidance of routine physical activity

During headache at least 1 of the following

- Nausea and/or vomiting
- Photophobia and phonophobia

With Aura:

At least 2 attacks

1 or more of the following fully reversible aura symptoms

- Visual, sensory, speech/language, motor, brainstem, retinal

At least 2 of the following 4 characteristics:

- At least one aura symptom spreads gradually over 5 minutes, and/or two or more symptoms occur in succession
- Each individual aura symptom lasts 5-60 minutes
- At least one aura symptom is unilateral
- Aura is accompanied, or followed within 60 minutes, by headache

Transient ischemic attack has been excluded

Migraine Treatment Recommendations

Level A:	Level B:
All triptans	**Anti-emetics:** IV Metoclopramide & Prochlorperazine
DHE Nasal Spray	**Anti-dopamine:** IV Chlorpromazine & Droperidol IV
NSAIDs: Diclofenac, aspirin, naproxen, ibuprofen	**Ergots:** IM/IV DHE
Acetaminophen Acetaminophen/aspirin/caffeine 500/500/130 mg Acetaminophen 1000 mg (for non-incapacitating attacks)	**NSAIDS**: Ketorolac
Butorphanol nasal spray	**Opioids**: Codeine/acetaminophen, Tramadol/acetaminophen

Marmura MJ. Headache 2015

Treatment of a migraine attack is managed primarily by the PCP who may not have the appropriate expertise

Clinical Insights into Patient Experience and Prognosis

Patients struggle to receive appropriate treatment

- PCPs will often recommend multiple therapies (OTC, herbals, opioids) over the course of months and even years before obtaining appropriate therapy

"You're looking to wait six months to get treatment… primary care treats the vast majority of migraine "
- Health Plan

Contraindications and adverse effects prevent patients from receiving adequate therapy

- Many therapies are associated with adverse effects: cardiovascular, gastrointestinal, sedation
- Contraindications include pregnancy and breastfeeding

"Patients who failed a triptan or don't refill it are getting opioids and barbiturates" – ***Headache Specialist***

Poorly treated patients are increased risk for transitioning to chronic migraine

- Non-adherence to medication
- Overuse of medication, caffeine
- Increased headache frequency
- Frequently, receive opioids or barbiturates (~40%)

"We don't get diagnosis codes on opioids [to manage them in migraine]"
-PBM

Nerivio (recently approved disposable device) for Acute Treatment and Cluster Is Favorable Among Participants

Participants agreed the clinical data is sufficient to be considered in their review of therapies for acute migraine

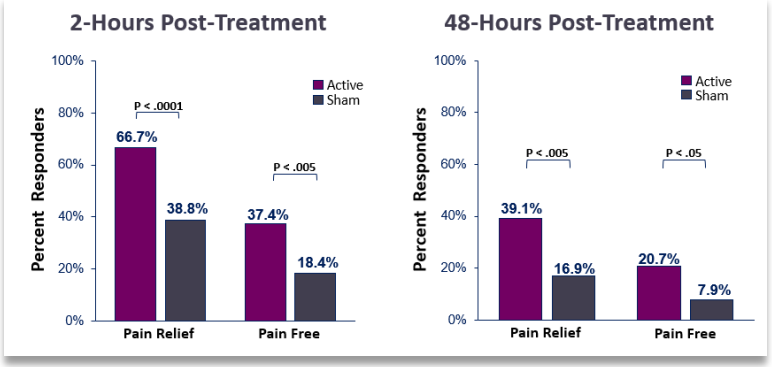
- Health plans recommend registering with MediSpan and First Data to enable the placement on the pharmacy benefit and proper adjudication
- Allowing PBMs to manage the distribution and adjudication would be preferable for most plans
- Positioning the product for placement on the medical benefit would not be covered

Participants suggested the following evidence or endpoints which would assist in the renewals/reauthorizations of the product:

- Reduction in ER visits
- Medication-sparing (triptans, opioids)
- Decrease in office visits
- PROs – practical and clinically in use
- Use in pregnancy
- Decrease in exacerbations / attacks
- Reduction in medication overuse migraines

Participants recognized the positioning of a device as a good option especially for those patients who may be intolerant, contraindicated or at risk for rebound migraine

- Validation of a patient ability to use the device effectively would be required by payers
- Communications should tell the story of the value of the product in a direct and succinct manner
    - Burden and risk of patients with migraine
    - Clinical evidence of the device
    - Potential cost implication of patients using the device
- Training and patient support to ensure appropriate utilization (hub services, provider certifications and patient training)



The expected price range for such a device would be between $300 to $500

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Novel Agents for Acute Migraine: Ditans and Gepants

	REYVOW (lasmiditan) (Eli Lilly/CoLucid)	NURTEC ODT (rimegepant) (Biohaven)	UBRELVY (Ubrogepant) (Allergan)
Class	Ditan	Gepant	Gepant
Indication	Acute	Acute	Acute
Mechanism	5-HT_{1F} Receptor Agonist*	Small Molecule CGRP Receptor Antagonist	Small Molecule CGRP Receptor Antagonist
Formulation	Oral Tablet	Orally Disintegrating Tablet	Oral Tablet
2-Hour Pain Free Vs Placebo	SPARTAN - Phase 3 SAMUARI - Phase 3	301 - Phase 3 302 - Phase 3	Achieve I - Phase 3 Achieve II - Phase 3
Study 1	38.6% vs 21.3%	19.2% vs 14.2%	21.2% vs 11.8%
Study 2	32.2% vs 15.3%	19.6% vs 12.0%	21.8% vs 14.3%

*Launched since date of meeting

Payers will likely wait for all newer agents to be approved then review the entire class

Ditans
(lasmiditan)

- Because it targets 5-HT1F it is not considered a vasoconstrictor with similar efficacy to triptans
- Dizziness was seen in about 18 percent of patients in the clinical trials
- Likely to receive a driving restriction in the label
- Expectations to receive controlled substance classification, awaiting DEA

Participants expressed it will likely step through 2 triptans

"The difference between a C4 and C5 is huge… its going to restrict access"
— Health Plan

Gepants- pipeline
(rimegepant, ubrogepant)

- New oral options that targets CGRP a migraine attack (acute setting)
- Studied in patients who failed triptan; triptan-naïve and concomitant use of triptan
- Not anticipated to cause medication overuse headache
- Operate peripherally, not vasoconstrictive
- Side effect profile is promising – no sedation and minor nausea

Participants were confused with the perceived low proportion of patients who achieved a response – recommend messaging describing differences between 2-hour Pain Free and 2-hour Pain-Relief endpoints

Payers would likely block the new agents

- Wait to review all four of the agents together, ~6 months
- Medicare coverage to be determined
- May be rolled out under PA

Formulary exception/appeal may allow access – payers will assess demand based on submitted appeals

"If we are getting all these appeals… overturning denials… So we will take it back and look at it again."
— IDN

Opportunities for Potential Positioning of the Novel Agents

Payer Unmet Need in Managing Acute Migraine

1. Segment plans, PBMs and IDNs which separate management of Acute Migraine, Migraine Prevention and Cluster Headache

2. Identify and quantify patients who are:
   - Cardiovascular risk (contraindicated)
   - Unable to tolerate the sedative effects of triptans
   - At risk for medication overuse migraine

3. Potential outcomes of interest with payers:
   - Decrease in ER visits
   - Hospitalizations
   - Outpatient visits
   - Medication sparing (opioids; triptans)

4. Engage in a campaign to educate PCPs on the treatment of migraine and the specific needs of patients who might not be candidates for triptans

Definitions of Chronic Migraine and Treatment Options

Chronic Migraine	
High volume of attacks (more than 15 days/month) for more than 3 months	8 days/month with migraine symptoms or headache relieved by triptan
A minimum of 5 attacks meet criteria for migraine with or without aura	Less likely to be employed; more likely to overuse, and more refractory to treatment (2-3 acute options)

ICHD 3 Cephalalgia 2018; 38:1-21
Marmura MJ. Headache 2015
Silberstein SD. Neurology 2012

Migraine Preventive Treatments

Level A Effective	Level B: Probably effective	Level C: Possibly effective	Level U: Inadequate or conflicting	Ineffective
AEDs Divalproex Valproate Topiramate **B-blockers** Metoprolol Propranolol Timolol ***CGRP MAB** Erenumab aooe Fremanezumab vfrm Galcanezumab gnlm	**SNRI/TCA** Amitriptyline Venlafaxine **B-blockers** Atenolol Nadolol **ARB** Candesartan	**ACE** Lisinopril **α-agonists** Clonidine Guanfacine **AEDs** Carbamazepine **B-blockers** Nebivolol Pindolol **Leukotriene Antag** Cyproheptadine	**CA inhibitor** Acetazolamide **Anticoagulants** Coumadin Picotamide **SSRI /SSNR1** Fluvoxamine Fluoxetine **AEDs** Gabapentin **TCAs** Protriptyline **B-blockers** Bisoprolol **Ca++ Blockers** Nicardipine Nifedipine Nimodipine Verapamil	**NOT effective** Lamotrigine **Probably NOT effective** Clomipramine **Possibly NOT effective** Clonazepam Oxcarbazepine

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The expansion of the prevention category offers challenges and opportunities for plans, providers and manufacturers

The influx of new agents targeted to migraine

- The CGRPs are projected a 3-fold increase in sales by 2020 (Burke et al. 2019)
- 4 new agents expected for approval by Q2 2020
- Lack of perceived clinical differentiation will fuel contract negotiations with multiple options

Low awareness of the diagnosis of conditions

Plans question the competency of a typical family practice physician or their mid level providers to differentiate between acute and chronic migraine

Volume of patients and scarce credentialed providers

- Introduction of new agents attracts an influx of patients hoping to find an agent that works for them
- Number of neurologists is decreasing every year
  - 500 headache specialists to treat 40 million patients
- Several plans may not have access to specialists

Patient economic burden is undefined and unrecognized in the data

- Many health plans do not have the ability to stratify patients within the migraine category (acute, prevention, cluster)
- Few studies to effectively represent the economic burden relieved by effective prevention of migraine

- **Plans will likely aim to restrict access to newer agents to drive rebate revenue**
- **Plans and providers will seek education on the diagnosis and treatment of chronic migraine**
- **Innovative plans will separate the acute from prevention – but others will struggle**
- **Plans will respond to provider requests for denials to maintain provider satisfaction**
- **Plans need assistance identifying the appropriate patient within their populations**
- **Opportunities to quantify the patient burden include medication-sparing (triptan, opioid)**

Only the CGRPs are uniquely indicated to prevent migraine – but payers will likely continue to favor generic options

Over 40 drug therapies used to prevent migraine

- Variable rates of response
- Rarely curative
- Can have adverse effects

2 neurostimulation devices FDA cleared for migraine prevention

- Supraorbital transcutaneous nerve stimulator, Single pulse transmagnetic stimulator

"We want to make sure they tried a preventative treatment, not just a triptan, [prior to a CGRP]"
- PBM

Only 8 agents FDA approved for prevention of migraine

- Propranolol,
- Timolol,
- Dilvalproex sodium,
- Topiramate,
- Onabotulinum toxin A

Unique Headache Indications

- Erenumab-aooe,
- Fremanezumab-vfrm,
- Galcanezumab-gnlm,

Lipton Headache 2015

The pipeline activity of the CGRP class will likely draw increased attention and scrutiny of migraine

	Indications			Administration		
	Acute / Episodic	Preventation	Cluster Headache	Oral	SQ	IV
Erenumab (Aimovig)		X			X	
Galcanezumab (Emgality)		X	X		X	
Fremanezumab (Ajovy)		X			X	
Investigational Agents						
Eptinezumab	*x*	*x*				*x*
Gepants (category)	*x*			*x*		

The introduction and expansion of CGRPs is driving greater awareness of migraine

- Current awareness of the differentiating factors three indications (acute, preventative, and cluster headache) remains low
- Payers will likely favor agents on the pharmacy benefit (SC and oral)
- IV products would likely need differentiating clinical evidence to gain coverage

Payers' limited familiarity with migraine and cluster opens potential study opportunities to improve CGRP positioning

Participants expressed the need for greater understanding on:

- Burden of the adverse effects:
  - Sedation
  - Driving impairment
  - Medication overuse headaches
  - Non-adherence to medication (triptans, topiramate, divalproex, beta-blockers, antidepressants
- Patient characteristics contraindicated for triptans
  - History of coronary artery disease, stroke, or transient ischemic attack
  - Peripheral vascular disease
  - Uncontrolled hypertension
  - Ischemic bowel disease
  - Pregnancy

Some payers may seek other measures beyond clinical trials for differentiation:

Burden:

- Overuse of medication: patients who receive contraindicated therapy (CV, gastrointestinal events, pregnancy, other)
- Switching practices, (frequency, outcomes)
- Non-adherence to medication (triptans, topiramate, divalproex, beta-blockers, antidepressants) due to adverse events

Reduction in economic outcomes: ER visits, outpatient visits, hospitalizations

Reduction in medication overuse or misuse: triptans, opioids

Patient Reported Outcomes: practiced or performed in the clinic

…I like adjusted quality-of-life here and PROs and patient satisfaction surveys because [of the significant] indirect costs"
–Health Plan

CGRP product exclusions from formulary may indicate unrecognized clinical differentiation, limited indications and perhaps a unique MOA

Payers generally perceive the CGRPs to be clinically equivalent

Drivers of formulary exclusions with CGRPs

- Undifferentiated clinical evidence and lack of real-world data
- Contracting based on one-of-two scenarios – net cost goal

…we've looked at them all and found them to be clinically equivalent. So you don't need them all… throw them over to trade and they do their thing."
–IDN

Influence of Indications on Contracting Negotiations

- In the absence of differentiation, more indications (acute, preventive and/or cluster headache) would likely have prove an advantage
- Fulfills goal of a stable formulary over a longer time period

"Emgality… may have a little bit of leg up [with the cluster headache indication]"
– PBM

Value of a Different MOA

- Several participants indicated decisions to restrict CGRPs include the decision to have a CGRP receptor and a ligand antagonist

Cluster Headache

Cluster Headache

MOST COMMON TRIGEMINAL AUTONOMIC CEPHALALGIA

LONGEST DURATION ATTACK TAC (15-180MIN)

LOWEST ATTACK FREQUENCY (1 QOD TO 8X DAY)

0.02%-0.1% OF POPULATION; MORE COMMON IN MEN

FIRST ATTACK CAN OCCUR ANY AGE, AVERAGE AGE IS 31.5

KNOWN AS "SUICIDE" HEADACHE

Definitions for Cluster Headache

At least 2 cluster periods lasting from 7 days to 1 year (untreated)

- For episodic separated by pain free periods lasting at least 3 months (for episodic), or less than 3 months (for chronic)

At least 5 attacks fulfilling below

- Severe or VERY severe unilateral orbital/supraorbital and/or temporal pain, lasting 15min-180 min if untreated
- 1 attack every other day up to 8 attacks per day

Either or both of the following

- A sense of restlessness or agitation
- At least one of the following symptoms or signs, ipsilateral to the headache
  - conjunctival injection and/or lacrimation
  - nasal congestion and/or rhinorrhea
  - eyelid edema
  - Forehead and facial sweating
  - Miosis and/or ptosis

Episodic cluster headache is more common than chronic

Cluster headaches are difficult to treat and clinically manage

Cluster Attack	Cluster Cycle or Period	
Most often same time of day (later afternoon/after dinner or middle of the night	Seasonal Variation	90% have at least 1-month remission between cycles
During cycle patients speak of self-harming behavior	Lasts 2-12 weeks	~10% don't have remission (chronic cluster)

About 75% of patients are misdiagnosed, often not receiving accurate diagnosis for a decade

Cluster headaches may involve pain around one eye, along with drooping of the lid, tearing and congestion on the same side as the pain

AHS Guideline Recommended Treatment for Cluster Headaches

Acute/Episodic Cluster Headache

Level A:

Oxygen via loose face mask, 7-10 Liters, over 20-30 minutes
Sumatriptan
- nasal spray
- injection

Zolmitriptan nasal

Level B:

Zolmitriptan oral
Anti-dopamine:
IV Chlorpromazine & Droperidol IV
Ergots: IM/IV DHE
NSAIDS: Ketorolac
Opioids: Codeine/acetaminophen, Tramadol/acetaminophen

Level C

Octreotide SQ (not used in US)

Level U

Ergotamines: DHE Spray

Cluster Headache Prevention

Level A:

Greater Occipital Nerve Block

Level B

Civamide nasal spray
(not available in the US)

Level C

Lithium
Verapamil
Warfarin
Melatonin

Treatment Additions Since Guideline Publications

EMGALITY (galcanezumab)

- Only FDA approved for Episodic Cluster headache
- 300 mg once monthly during cycle
- Pre-filled syringe
- May be stopped between cluster cycles

gammaCore

- Vagal nerve stimulator
- Patients applies unilaterally attack for 2 minutes
- Maximum 24 stimulations/day
- Cleared for acute treatment and prevention of migraine

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Payers may recognize the clinical distinction between cluster headaches and migraine, but struggle to separate management

"In about 30% of patients with cluster headache, it takes them a decade to actually get the diagnosis"
– Headache Specialist

Small population and heavy patient burden

- Very small population (0.02%-0.1%)
- Patients not functional with severe pain
- Best treatment with specialist, not the ER

Accurate diagnosis

- Underdiagnosed – patients struggle to get appropriate diagnosis
- Overdiagnoses – PCPs/neurologist lack experience
- Excess scans and labs lead to increased costs and delay appropriate treatment

Specialist scarcity

- Patients may wait 6 months for appointment
- Neurologist prescriber often required but may not have expertise
- Headache specialist scarce (~500 in US)

"We require prescriber specialty"
– IDN

Payer Insights

- Payers need significant education in patient type, provider diagnosis, clinical symptoms and burden of disease
- Management of cluster separate from migraine is challenging
- Specialist access is a major problem for payers; a consult is necessary but fails to guarantee an accurate diagnosis
- CGRP is likely a first line options for accurate diagnosis of cluster headaches

"You can have your [CGRP] first-line [in cluster]"
- Health Plan

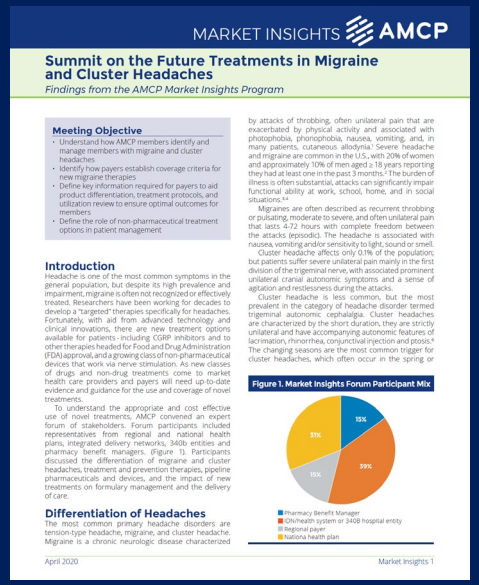
"[Cluster and migraine] just get lumped into the same category. I would have no way of pulling out [cluster]"
- Health Plan

"I think this access [to the appropriate provider] is probably the single biggest issue that I think we're facing in kind of looking in some of these therapies and some of these disease states. "
– Health Plan

Key takeaways

- Limited number of providers who specialize in headache treatment may impact access for patients – plans with PA requirining specialists may impact ability of patients to receive treatment
- Availability of novel agents are changing the way migraines are treated
  - Episodic
  - Chronic
  - Non-pharmacologic
- Low awareness of differentiation of migraine (episodic and chronic) and cluster headaches
- Opportunity for additional clinical education as additional treatment options become available for AMCP members to understand and manage this category

Look for the summary report in April issue of JMCP



MARKET INSIGHTS AMCP

Summit on the Future Treatments in Migraine and Cluster Headaches

Findings from the AMCP Market Insights Program

Meeting Objective

- Understand how AMCP members identify and manage members with migraine and cluster headaches
- Identify how payers establish coverage criteria for new migraine therapies
- Define key information required for payers to aid product differentiation, treatment protocols, and utilization review to ensure optimal outcomes for members
- Define the role of non-pharmaceutical treatment options in patient management

Introduction

Headache is one of the most common symptoms in the general population, but despite its high prevalence and impairment, migraine is often not recognized or effectively treated. Researchers have been working for decades to develop a "targeted" therapies specifically for headaches. Fortunately, with aid from advanced technology and clinical innovations, there are new treatment options available for patients - including CGRP inhibitors and to other therapies headed for Food and Drug Administration (FDA) approval, and a growing class of non-pharmaceutical devices that work via nerve stimulation. As new classes of drugs and non-drug treatments come to market health care providers and payers will need up-to-date evidence and guidance for the use and coverage of novel treatments.

To understand the appropriate and cost effective use of novel treatments, AMCP convened an expert forum of stakeholders. Forum participants included representatives from regional and national health plans, integrated delivery networks, 340b entities and pharmacy benefit managers. (Figure 1). Participants discussed the differentiation of migraine and cluster headaches, treatment and prevention therapies, pipeline pharmaceuticals and devices, and the impact of new treatments on formulary management and the delivery of care.

Differentiation of Headaches

The most common primary headache disorders are tension-type headache, migraine, and cluster headache. Migraine is a chronic neurologic disease characterized by attacks of throbbing, often unilateral pain that are exacerbated by physical activity and associated with photophobia, phonophobia, nausea, vomiting, and, in many patients, cutaneous allodynia.[1] Severe headache and migraine are common in the U.S., with 20% of women and approximately 10% of men aged ≥ 18 years reporting they had at least one in the past 3 months.[2] The burden of illness is often substantial, attacks can significantly impair functional ability at work, school, home, and in social situations.[3,4]

Migraines are often described as recurrent throbbing or pulsating, moderate to severe, and often unilateral pain that lasts 4-72 hours with complete freedom between the attacks (episodic). The headache is associated with nausea, vomiting and/or sensitivity to light, sound or smell.

Cluster headache affects only 0.1% of the population; but patients suffer severe unilateral pain mainly in the first division of the trigeminal nerve, with associated prominent unilateral cranial autonomic symptoms and a sense of agitation and restlessness during the attacks.

Cluster headache is less common, but the most prevalent in the category of headache disorder termed trigeminal autonomic cephalalgia. Cluster headaches are characterized by the short duration, they are strictly unilateral and have accompanying autonomic features of lacrimation, rhinorrhea, conjunctival injection and ptosis.[4] The changing seasons are the most common trigger for cluster headaches, which often occur in the spring or

Figure 1. Market Insights Forum Participant Mix

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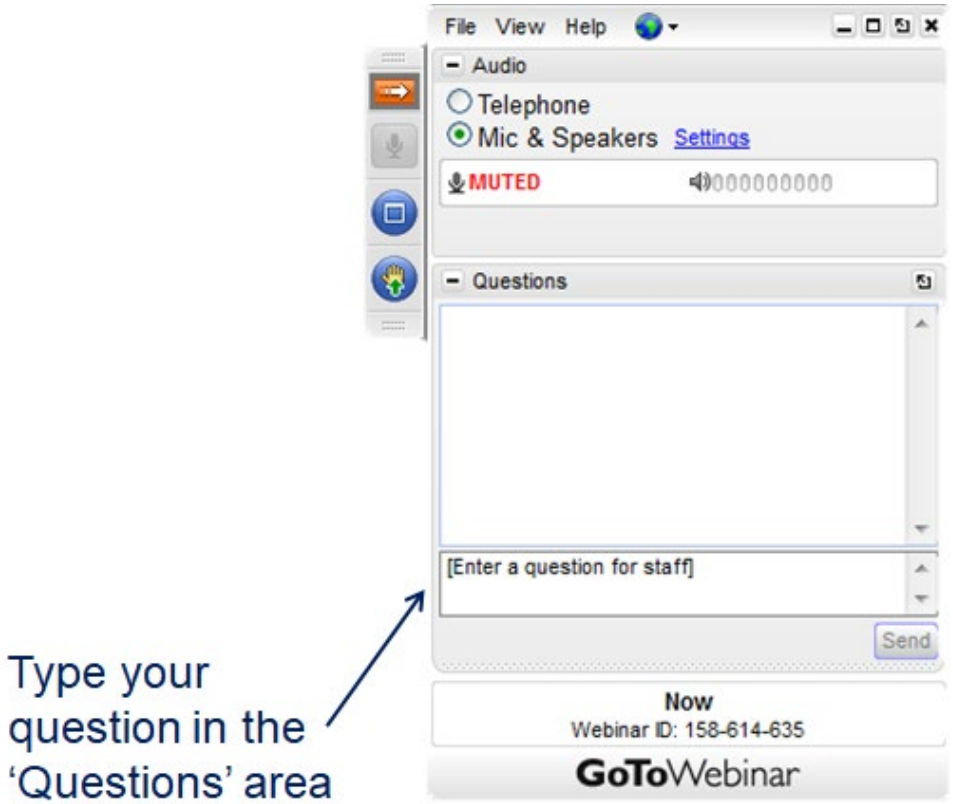

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