UPDATE ON CGRP INHIBITOR PRESCRIBING IN MISSISSIPPI MEDICAID

BACKGROUND

In 2018, a new class of medications, known as calcitonin gene-related peptide (CGRP) inhibitors, received FDA approval for the prevention of migraine headaches. [1] CGRP inhibitors are the first agents developed specifically for migraine prevention. CGRPs are vasoactive neuropeptides associated with pain whose levels are increased during a migraine. [2, 3] Monoclonal antibodies have been developed that target either CGRP or the CGRP receptor in the prevention migraines. Currently three monoclonal antibody CGRP inhibitors have been approved.

- Aimovig (erenumab-aooe) – approved May 17, 2018
- Ajovy (fremanezumab-vfrm) – approved September 14, 2018
- Emgality (galcanezumab-gnlm) – approved September 27, 2018[4]

With an estimated 39 million migraine sufferers in the U.S. annually, migraines are a serious public health issue. It is estimated that healthcare and lost productivity costs associated with migraines can be as high as $36 billion annually. [5] CGRP inhibitors have the potential to dramatically impact pharmacologic treatment approaches for migraine suffers.

At the September 2018 DUR Board Meeting, MS-DUR presented a report on the introduction of CGRP inhibitors for migraine prevention. The DUR Board provided recommendations for clinical criteria to be utilized by the Mississippi Division of Medicaid (DOM). The Board also recommended MS-DUR revisit this topic to assess the utilization of CGRP inhibitors in the spring of 2019. DOM implemented a manual prior authorization (PA) for CGRPs effective February 1, 2019 that can be found at https://medicaid.ms.gov/manual-prior-authorization-criteria/.

METHODS

A retrospective analysis was conducted using Mississippi Medicaid pharmacy and medical claims data across Fee-For-Service and the three coordinated care organizations [UnitedHealthcare (UHC), Magnolia Health (MAG), and Molina Healthcare (MOL)] for the period of May 2018 through February 2019. Pharmacy claims for three CGRP inhibitor agents [erenumab-aooe (Aimovig), fremanezumab-vfrm (Ajovy), and galcanezumab-gnlm)] were identified using their respective national drug codes (NDCs). For each CGRP inhibitor claim, the provider type was identified and

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[1] FDA. FDA approves novel preventive treatment for migraine. May 2018. https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm608120.htm. Accessed April 2019.

[2] Minor, D, et al. Pharmacotherapy: A Pathophysiologic Approach [Internet]. 10th ed. New York (NY): McGraw-Hill; c2017. Chapter 61: Headache Disorders.

[3] Bigal, ME, et al. Migraine in the Triptan Era: Lessons from Epidemiology, Pathophysiology, and Clinical Science. Headache. 2009 Feb;49 Suppl 1:S21-33.

[4] Drugs.com https://www.drugs.com/drug-class/cgrp-inhibitors.html. Accessed April 2019.

[5] Migraine Research Foundation. 2018. Available from: http://migraineresearchfoundation.org/about-migraine/migraine-facts/. Accessed April 2019.

designated as a neurologist, other type of physician, nurse practitioner affiliated with a neurologist, nurse practitioner not affiliated with a neurologist, or other provider. The total cost of each type of CGRP inhibitor treatment was calculated according to each pharmacy program. For beneficiaries with claims for any CGRP inhibitor treatment, their age, gender, and race were also identified.

RESULTS

Table 1 shows the demographic characteristics of beneficiaries with claims for CGRP inhibitors.

- A total of 74 beneficiaries have paid claims for CGRP inhibitors over the ten month period
- 66% of beneficiaries are ages 18-44 years
- 97% of beneficiaries are female and approximately 65% are Caucasian
- Neurologists and NPs associated with a neurologist comprise 78% of prescribers

TABLE 1: Characteristics of Beneficiaries with Claims for CGRP Inhibitors (May 2018 - February 2019)

	FFS	UHC	MAG	MOL	Total
AGE (years)					
18-44	6	14	27	2	49
>44	2	9	14	0	25
Total	*8*	*23*	*41*	*2*	*74*
GENDER					
Male	0	1	1	0	2
Female	8	22	40	2	72
Total	*8*	*23*	*41*	*2*	*74*
RACE					
Caucasian	6	17	23	2	48
Hispanic	0	1	0	0	1
African American	2	4	17	0	23
Other	0	1	1	0	2
Total	*8*	*23*	*41*	*2*	*74*
PROVIDER TYPE					
MD-Neuro	3	12	13	0	28
MD-Other	0	1	6	0	7
NP-Other	1	3	1	0	5
NP-Neuro	3	5	20	2	30
Other Provider	1	2	1	0	4
Total	*8*	*23*	*41*	*2*	*74*

Table 2 shows all paid claims for CGRP inhibitors by plan through February 2019.

- 77% of CGRP inhibitor claims occurred between December 2018 and February 2019

TABLE 2. Number of CGRP Claims (August 2018 - February 2019)			
Month	**Plan**	**Drug**	**Total # of claims**
Aug-18	Magnolia	Aimovig	1
Sep-18	Fee for Service	Aimovig	1
	Magnolia	Aimovig	2
Oct-18	Fee for Service	Aimovig	1
	United Health Care	Aimovig	4
		Ajovy	1
	Magnolia	Aimovig	9
Nov-18	Fee for Service	Aimovig	1
	United Health Care	Aimovig	3
		Ajovy	1
	Magnolia	Aimovig	10
		Ajovy	2
Dec-18	Fee for Service	Aimovig	1
	United Health Care	Aimovig	2
		Ajovy	3
	Magnolia	Aimovig	17
		Ajovy	4
	Molina	Aimovig	1
Jan-19	Fee for Service	Aimovig	3
	United Health Care	Aimovig	6
		Ajovy	5
		Emgality	1
	Magnolia	Aimovig	21
		Ajovy	6
		Emgality	1
Feb-19	Fee for Service	Aimovig	3
		Ajovy	1
	United Health Care	Aimovig	6
		Ajovy	7
		Emgality	1
	Magnolia	Aimovig	20
		Ajovy	7
		Emgality	2
	Molina	Ajovy	1
		Total	**155**

Table 3 shows a claims-level analysis of the total spend associated with each CGRP inhibitor.

- DOM has paid a total of $93,503 in payments to providers for CGRP inhibitors since May 2018; however 77% of claims occurred December 2018 – February 2019.
- The average paid claim for each agent:
    - Aimovig - $612
    - Ajovy - $568
    - Emgality - $681
- The average paid per claim for all CGRP inhibitors combined is $603/claim.

TABLE 3: Claims Level Total Spend by Drug

	FFS	MAG	UHC	MOL	Total Claims	Total Cost
Emgality	0	3	2	0	5	$3,406
Ajovy	1	19	17	1	38	$21,601
Aimovig	10	80	21	1	112	$68,496
TOTAL	11	102	40	2	155	$93,503

In addition to retrospective claims data analysis, MS-DUR compiled data collected from the PA units for FFS and the CCOs for all approvals and denials of manual PAs for CGRP inhibitors through March 2019.

Key Points:

- Manual PAs are required for an initial authorization (12 weeks) and for reauthorization.
- Across all plans (FFS and CCOs), 95 PAs have been approved and 142 have been denied.
- The primary reason noted for PA denials is failure of an appropriate trial of other agents. This was followed distantly by lack of diagnosis and lack in number of headache days.
- PA denials due to lack of approved provider type specified on the PA form for prescribing the CGRP agent does not appear to be a concern.
- There was limited data available to assess appropriateness for reauthorizations as most of the prescriptions are still in the initial authorization phase
    - However, the PA units did note some difficulty documenting *"Verified pharmacy prescription claims history of Aimovig, Ajovy or Emgality and demonstrated adherence"* when reauthorizing PAs due to CGRP samples provided to beneficiaries by their treating providers.

CONCLUSIONS AND RECOMMENDATIONS

With so many migraine sufferers unable to obtain significant symptom relief with prior therapies, CGRP inhibitors have the potential to make a tremendous impact on this segment of pharmacotherapy. Since their release in 2018, CGRP inhibitor utilization in MS Medicaid has been steadily increasing across all pharmacy programs. From data received from the PA units, it does not appear there are issues with beneficiary claims being denied due to lack of approved provider submission. The requirement of a trial of other agents prior to initiating CGRP inhibitors is helping drive appropriate prescribing. With an average cost of $603 per paid claim, it is imperative DOM monitor the utilization and outcomes associated with CGRP inhibitor therapy. At this time it is too early for outcomes to be assessed.

Recommendations:

1. MS-DUR will work with the DOM to assess outcomes associated with CGRP inhibitors. MS-DUR will specifically compare change in hospitalizations, ED visits, and utilization of rescue agents for beneficiaries diagnosed with both episodic and chronic migraine receiving CGRP inhibitors.