NC Division of Medical Assistance **Medicaid and Health Choice**
Outpatient Pharmacy **Effective Date: February 26, 2019**
Prior Approval Criteria **Amended Date:**
Migraine Therapy
Calcitonin Gene-Related Inhibitors

Therapeutic Class Code: H3F

Therapeutic Class Description: Migraine Therapy- Calcitonin Gene-Related Peptide Inhibitors

Medication	~~Generic Code Number(s)~~
Aimovig 70mg/ml autoinjector	~~44753~~
Aimovig 140mg/ml autoinjector	
Ajovy 225mg/1.5ml syringe	~~45306~~
Emgality 120mg/ml pen	~~40418~~
Emgality 120mg/ml syringe	
Emgality 100mg/ml syringe (set of 3)	
Emgality 120mg/ml pen	

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.
EPSDT does not require the state Medicaid agency to provide any service, product, or procedure
a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or

ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements
EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be accessed at https://medicaid.ncdhhs.gov/.

Indications: Indicated for the preventative treatment of migraines in adults (Aimovig, Ajovy, and Emgality 120mg/ml) and treatment of episodic cluster headache in adults (Emgality 100mg/ml (set of 3).

A. Preventative Treatment of Migraines (Aimovig, Ajovy, and Emgality 120mg/ml)
Initial Criteria for Coverage

1. Beneficiary has a diagnosis of migraine with or without aura based on International Classification of Headache Disorders criteria AND
2. Beneficiary is 18 years old or older AND
3. Beneficiary does not have medication over-use headache (MOH) AND
4. Beneficiaries that are women of childbearing age have had a negative pregnancy test at baseline AND
5. Beneficiary has 4 or more migraine days per month for at least 3 months AND
6. Beneficiary is utilizing prophylactic intervention modalities (e.g. behavioral therapy, physical therapy, life-style modifications) AND
7. Beneficiary has tried and failed at least a month or greater trial of medications from at least 2 different classes from the following list of oral medications:
    a. Antidepressants (e.g. amitriptyline, venlafaxine)
    b. Beta Blockers (e.g. propranolol, metoprolol, timolol, atenolol)
    c. Anti-epileptics (e.g. valproate, topiramate)
    d. Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g. lisinopril, candesartan)
    e. Calcium Channel Blockers (e.g. verapamil, nimodipine)
8. Initial approvals for up to a 3 month duration for Aimovig, Emgality, Ajovy monthly dosing
9. Initial approvals for up to a 6 month duration for Ajovy quarterly dosing

Continuation of Coverage (renewal request) (Aimovig, Ajovy, and Emgality 120mg/ml)

1. Beneficiary has demonstrated significant decrease in the number, frequency, and/or intensity of headaches AND
2. Beneficiary had experienced an overall improvement in function with therapy
3. Beneficiary continues to utilize prophylactic intervention modalities (e.g. behavioral therapy, physical therapy, life-style modifications) AND
4. Beneficiaries that are women of childbearing age continue to be monitored for pregnancy status AND
5. Beneficiary is not experiencing unacceptable toxicity (e.g. intolerable injection site pain, constipation) AND

6. Length of therapy may be approved for up to 12 months

B. Treatment of Episodic Cluster Headache in Adults (Emgality 100mg/ml (set of 3)

Initial Criteria for Coverage

1. Beneficiary has a diagnosis of Episodic Cluster Headache with at least two cluster periods lasting from 7 days to 1 year (when untreated) and separated by pain-free remission periods of at least 3 months AND
2. Beneficiary is 18 years old or older AND
3. Beneficiaries that are women of childbearing age have had a negative pregnancy test at baseline AND
4. Beneficiary is utilizing prophylactic intervention modalities (e.g. medication therapy).
5. Beneficiary is receiving no more than 300mg (administered as three consecutive injections of 100mg each) at the onset of the cluster headache period, and then monthly until the end of the cluster headache period.
6. Initial approvals for up to a 3 month duration

Continuation of Coverage (renewal request) (Emgality 100mg/ml (set of 3)

1. Beneficiary has demonstrated decreases in the length, number, frequency, and/or intensity of headaches and/or a decrease in the length of the cluster period AND
2. Beneficiary had experienced an overall improvement in function with therapy
3. Beneficiary continues to utilize prophylactic intervention modalities (e.g. behavioral therapy, physical therapy, life-style modifications, medications) AND
4. Beneficiaries that are women of childbearing age continue to be monitored for pregnancy status AND
5. Beneficiary is not experiencing unacceptable toxicity (e.g. intolerable injection site pain, constipation) AND
6. Length of therapy may be approved for up to 12 months

References

1. Aimovig package insert, Amgen, Inc., Thousand Oaks, CA., May 2018.
2. Ajovy package insert, Teva Pharmaceuticals, USA, Inc., North Wales, PA. updated September 2018.
3. Emgality package insert, Eli Lilly and Co., Indianapolis, IN., updated September 2018. updated June 2019

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Criteria Change Log

02/26/2019	Criteria effective date
	Added coverage for Episodic Cluster Headache in Adults