NC Division of Medical Assistance **Medicaid**
Outpatient Pharmacy **Effective Date: February 26, 2019**
Prior Approval Criteria
Migraine Therapy
Calcitonin Gene-Related Inhibitors **Amended Date: January 1, 2024**

Therapeutic Class Code: H3F
Therapeutic Class Description: Migraine Therapy- Calcitonin Gene-Related Peptide Inhibitors

Medication
Preventative treatment of migraines in adults:
Aimovig 70mg/ml autoinjector
Aimovig 140mg/ml autoinjector
Ajovy 225mg/1.5ml autoinjector
Ajovy 225mg/1.5ml syringe
Emgality 120mg/ml pen
Emgality 120mg/ml syringe
Emgality 120mg/ml pen
Nurtec ODT 75 mg tablets
Qulipta tablets
Vyepti 100 mg/ml vial
Treatment of episodic cluster headache in adults
Emgality 100mg/ml syringe (set of 3)
Acute Treatment of Migraines, with or without aura
Nurtec ODT 75 mg tablets
Ubrelvy 50 mg tablets
Ubrelvy 100 mg tablets

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.

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

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***NCTracks Provider Claims and Billing Assistance Guide*:**
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page:
https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

A. Preventative Treatment of Migraines- injectable (Aimovig, Ajovy, Emgality 120mg/ml, and Vyepti)

Initial Criteria for Coverage

1. Beneficiary has a diagnosis of migraine with or without aura based on International Classification of Headache Disorders criteria;
2. Beneficiary is 18 years old or older;
3. Beneficiary does not have medication over-use headache (MOH);
4. Beneficiaries that are women of childbearing age have had a negative pregnancy test at baseline;(not required for Nurtec ODT or Qulipta)
5. Beneficiary has 4 or more migraine days per month for at least 3 months;
6. Beneficiary is utilizing prophylactic intervention modalities (e.g. behavioral therapy, physical therapy, life-style modifications) ;
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, or Ajovy monthly dosing; and

9. Initial approvals for up to a 6-month duration for Ajovy quarterly dosing and Vyepti.

B. Preventative Treatment of Migraines- oral (Nurtec ODT, Qulipta)

Initial Criteria for Coverage

1. Beneficiary has a diagnosis of migraine with or without aura based on International Classification of Headache Disorders criteria;

2. Beneficiary is 18 years old or older;

3. Beneficiary does not have medication over-use headache (MOH);

4. Beneficiary has 4 or more migraine days per month for at least 3 months;

5. Beneficiary is utilizing prophylactic intervention modalities (e.g. behavioral therapy, physical therapy, life-style modifications) ;

6. Beneficiary has tried and failed at least 2 preferred injectable CGRPs

7. For Nurtec ODT only:

   a. Beneficiary must NOT be concurrently using a strong CYP3A4 inhibitor;

   b. Beneficiary must NOT have end-stage renal disease (creatinine clearance [CrCl] < 15 mL/min);

8. Initial approvals for up to a 3-month duration for Nurtec ODT, Qulipta,

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

1. Beneficiary has demonstrated significant decrease in the number, frequency, and/or intensity of headaches;

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);
4. Beneficiaries that are women of childbearing age continue to be monitored for pregnancy status;
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.

C. 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;
2. Beneficiary is 18 years old or older;
3. Beneficiaries that are women of childbearing age have had a negative pregnancy test at baseline;
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; and
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;
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);
4. Beneficiaries that are women of childbearing age continue to be monitored for pregnancy status;
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

D. Acute Treatment of Migraines (Nurtec ODT 75mg and Ubrelvy 50 mg & 100 mg tablets)

Initial Criteria for Coverage

1. Beneficiary must be ≥ 18 years of age;
2. Beneficiary must have a diagnosis of migraine, with or without aura;
3. Beneficiary must NOT have headache frequency ≥ 15 headache days per month during the prior 6 months;
4. Beneficiary must NOT be concurrently using a strong CYP3A4 inhibitor;
5. Beneficiary must NOT have end-stage renal disease (creatinine clearance [CrCl] < 15 mL/min);
6. Beneficiary must have tried and failed, or have contraindication to, ≥ 2 preferred triptans.

Renewal Criteria

1. Beneficiary must continue to meet the above criteria;
2. Beneficiary must demonstrate resolution in headache pain or reduction in headache severity, as assessed by prescriber; AND
3. Beneficiary has not have experienced any treatment-restricting adverse effects (e.g., nausea, somnolence, dry mouth).

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
4. Ubrelvy [package insert]. Madison, NJ; Allergan; December 2019.
5. Nurtec ODT [package insert]. New Haven, CT; Biohaven. February 2020. Updated May 2021.
6. Qulipta [package insert]. Abbvie; October, 2021.Updated May 2023
7. Vyepti [package insert]. Bothell, WA; Lundbeck Seattle; February 2020.

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Criteria Change Log

02/26/2019	Criteria effective date
12/04/2019	Added coverage for Episodic Cluster Headache in Adults
3/11/2021	Added Ubrelvy
3/11/2021	Added Nurtec ODT and Vyepti
04/01/2022	Add coverage for preventative treatment for Nurtec ODT Add Qulipta
01/01/2024	Add Vyepti to continuation criteria
01/01/2024	Remove "Beneficiary must have tried and failed ≥ 1 of the following: NSAID, nonopioid analgesic, acetaminophen, OR caffeinated analgesic combination; AND" from Ubrelvy and Nurtec
01/01/2024	Separated oral and injectable prophylaxis agents Added step through 2 preferred injectable CGRP to get oral prophylaxis agents Removed Health Choice