Clinical Policy: Anti-Migraine Agents

Reference Number: **OH.PHAR.PPA.34**
Effective Date: 11.2019
Last Review Date: 6.2022
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

- The number of tablets/doses allowed per month is restricted based on the manufacturer's package insert and/or Buckeye Health plans quantity limits.

CNS AGENTS: ANTI-MIGRAINE AGENTS – ACUTE MIGRANE TREATMENT

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
NARATRIPTAN (GENERIC OF AMERGE®) RIZATRIPTAN TABLETS (GENERIC OF MAXALT®) RIZATRIPTAN ODT (GENERIC OF MAXALT-MLT®) SUMATRIPTAN TABLETS, NASAL SPRAY, INJECTION (GENERIC OF IMITREX®)	NURTEC™ ODT (rimegepant)*	ALMOTRIPTAN (generic of Axert®) CAFERGOT® (ergotamine w/caffeine) ELETRIPTAN (generic of Relpax®) ERGOMAR® (ergotamine) FROVA® (frovatriptan) MIGERGOT® (ergotamine w/caffeine) MIGRANAL® (dihydroergotamine) ONZETRA™ XSAIL™ (sumatriptan) REYVOW™ (lasmiditan) SUMAVEL DOSEPRO® (sumatriptan) TOSYMRA® (sumatriptan) TREXIMET® (sumatriptan/naproxen) TRUDHESA (dihydroergotamine) UBRELVY™ (ubrogepant)* ZOLMITRIPTAN (generic of Zomig®) ZOLMITRIPTAN ODT (generic of Zomig ZMT®) ZOMIG® NASAL SPRAY (zolmitriptan)

*Quantity limit is 8 per 30 days

CNS AGENTS: ANTI-MIGRAINE AGENTS – CLUSTER HEADACHE TREATMENT

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
VERAPAMIL (Generic of Calan®) VERAPAMIL SR/ER (Generic of Calan SR®, Isoptin SR®, Verelan®)	EMGALITY™ (galcanezumab)

CNS AGENTS: ANTI-MIGRAINE AGENTS – PROPHYLAXIS TREATMENT

NO PA REQUIRED "PREFERRED" (Trials of at least 3 controller medications)	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
Cardiovascular Agents: Beta-blockers CNS Agents: Anticonvulsants CNS Agents: Serotonin-norepinephrine reuptake inhibitors CNS Agents: Tricyclic antidepressants	AJOVY™ (fremanezumab-vfrm) * AIMOVIG™ (erenumab-aooe) †	EMGALITY™ (galcanezumab) NURTEC™ ODT (rimegepant)** QULIPTA (atogepant)

†Initial Dose is limited to 70mg once monthly; may request dose increase if 70mg fails to provide adequate relief over two consecutive months.

*675mg doses (quarterly administration) will not be authorized until patient has demonstrated efficacy of medication for at least 90 days.

**Nurtec ODT quantity limit is 18 per 30 days for prophylactic treatment.

FDA Approved Indication(s)

- Refer to Clinical Pharmacology or other appropriate clinical resource for FDA approved indications

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that the medications listed in the above tables are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Migraine headaches, Acute (must meet all)**:**

1. Member must meet labeled age requirements for requested medication;
2. For a non-preferred medication, the member must have had an inadequate clinical response to preferred alternatives, including a trial of at least two weeks with at least one medication requiring step therapy unless one of the following:
    a. Allergy to preferred medications
    b. Contraindication to all preferred medications
    c. History of unacceptable/toxic side effects to at least two preferred medications

3. For a medication requiring step therapy the member must have had an inadequate clinical response to preferred alternatives, including a trial of at least two weeks with at least two medications not requiring prior approval unless one of the following:
    a. Allergy to preferred medications
    b. Contraindication to all preferred medications
    c. History of unacceptable/toxic side effects to at least two preferred medications.

Approval duration: 180 days

B. Migraine headaches, Prophylaxis (must meet all**)**

1. Member must have one of the following diagnoses:
    a. Episodic migraine with the following frequencies of migraine:
        i. 4 to 15 headaches per 30 days measured over 90 consecutive days and headache duration of longer than 4 hours per day or longer during an attack on average.
    b. Chronic migraine with the following frequencies of migraine:
        i. 15 or more headaches per 30 days measured over 90 consecutive days and headache duration of longer than 4 hours per day or longer during an attack on average
2. Member must meet labeled age requirements for requested medication;
3. For a medication requiring step therapy, there must have been inadequate clinical response to a trial of at least 30 days each to at least 3 controller migraine medications (i.e., beta- blockers, anticonvulsants, tricyclic antidepressants, and/or serotonin-norepinephrine reuptake inhibitors) unless one of the following:
    a. Allergy to preferred medications
    b. Contraindication to three preferred medications
    c. History of unacceptable/toxic side effects to at least three preferred medications

4. For a non-preferred medication drug there must have been inadequate clinical response to a trial of at least 30 days each to at least 3 controller migraine medications (i.e., beta-blockers, anticonvulsants, tricyclic antidepressants, and/or serotonin-norepinephrine reuptake inhibitors) AND an inadequate clinical response to a trial of at least 30 days of one step therapy required preferred medication unless one of the following:
   a. Allergy to preferred medications
   b. Contraindication to three preferred medications
   c. History of unacceptable/toxic side effects to at least three preferred medications
5. Initial authorization will be limited to 180 days with objective documentation of severity, frequency, and number of headache days per month (preferably a headache diary). Re-authorization for 365 days will be allowed based upon evidence of improved headache control (preferably a headache diary or other objective documentation of severity, frequency, and number of headache days per month).

Approval duration:
Initial authorization: 180 days
Subsequent authorizations: 365 days

C. Cluster headaches (must meet all)
1. Diagnosis of episodic cluster headaches;
2. Member must meet labeled age requirements for requested medication;
3. Failure of at least one medication not requiring prior approval unless one of the following:
   a. Allergy to preferred medications
   b. Contraindication to all preferred medications
   c. History of unacceptable/toxic side effects to at least one preferred medication
4. At least 5 attacks within 30 days
5. Attacks characterized by severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15 to 180 minutes when untreated; during part (but less than half) of the time-course of cluster headache, attacks may be less severe and/or of shorter or longer duration;
6. Member must have one or more of the following symptoms:
   a. At least one of the following ipsilateral to the headache:
      i. Conjunctival injection and/or lacrimation
      ii. Nasal congestion and/or rhinorrhea
      iii. Eyelid edema
      iv. Forehead and facial sweating
      v. Miosis and/or ptosis
   b. A sense of restlessness or agitation
7. Attacks have a frequency between one every other day and eight per day; during part (but less than half) of the active time-course of cluster headache, attacks may be less frequent;

8. Member's diagnosis not better accounted for by another ICHD-3 diagnosis;
9. At least two cluster periods lasting from seven days to one year (when untreated) and separated by pain-free remission periods of 90 days or more
10. Failure or intolerance to verapamil titrated at least to a dose of 480mg daily (may need to be combined with glucocorticoids as adjunctive therapy for more rapid relief until verapamil is titrated)

Approval duration: 180 days

II. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 for Medicaid or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
CGRP: calcitonin gene-related peptide

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Cardiovasular Agents: Beta-blockers	Migraine prophylaxis Refer to prescribing information or Micromedex	Refer to prescribing information or Micromedex
CNS Agents: Anticonvulsants	Migraine prophylaxis Refer to prescribing information or Micromedex	Refer to prescribing information or Micromedex
CNS Agents: Tricyclic antidepressants	Migraine prophylaxis Refer to prescribing information or Micromedex	Refer to prescribing information or Micromedex
CNS Agents: Serotonin-norepinephrine	Migraine prophylaxis Refer to prescribing information or Micromedex	Refer to prescribing information or Micromedex
Triptans	Migraine prophylaxis or episodic cluster headache (imitrex injection, Sumavel Dosepro®) Refer to prescribing information or Micromedex	Refer to prescribing information or Micromedex

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications

- Contraindication(s):
  - Hypersensitivity
  - All triptans:
    - History of coronary artery disease or coronary vasospasm; symptomatic Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders; history of stroke, transient ischemic attack, or hemiplegic or basilar migraine, or peripheral vascular disease; ischemic bowel disease; or uncontrolled hypertension.
    - Recent (within 24 hours) used of another 5-HT1 agonist (e.g., another triptan), or an ergotamine-containing medication.
  - Relpax: within at least 72 hours of treatment with the following potent CYP3A4 inhibitors: ketoconazole, itraconazole, nefazodone, troleandomycin, clarithromycin, ritonavir or nelfinavir.
  - Imitrex, Zomig: use concurrently or within 2 weeks of discontinuation of an MAO-A inhibitor or non-selective MAO inhibitor.

- Boxed warning(s):
  - Treximet: risk of serious cardiovascular and gastrointestinal events
  - All other triptans: none reported

IV. Dosage and Administration

A. Varies by drug product. See FDA approved dosing and administration.

V. Product Availability

A. Varies by drug product. Refer to Clinical Pharmacology or other appropriate clinical resource for product availability.

VI. References

Refer to package insert

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.19	
Added Tosymra as a non-preferred Serotonin 5-HT1 Receptor Agonist	03.20	
Added ergotamine agents for acute migraine treatment. Added Nurtec ODT as new step therapy agent.	08.20	
Policy updated. Added Ajovy and Emgality as step therapy preferred agents	11.20	

Policy updated. Added criteria for chronic migraine prophylaxis. Added Emgality to pa required "non-preferred" and Aimovig to step therapy "preferred"	07.21	
Added Nurtec ODT to PA required, non-preferred for migraine prophylaxis. Added quantity limit for Nurtec ODT of 8 per 34 days. Removed stated for migraine prophylaxis that re-authorization may be managed in consultation with a specialist.	11.21	
Quarter 1 2022 review – Added Trudhesa to PA required, non-preferred for acute migraine treatment. Added Qulipta to PA required, non-preferred for migraine prophylaxis. Updated quantity limits for Nurtec ODT to 8 per 30 days for acute migraine treatment	2.22	
Quarter 2 2022 review – Added additional criteria related to initial authorization and subsequent authorizations for migraine prophylaxis. Added quantity limit for Nurtec ODT when being used as prophylactic treatment	6.22	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.