Initial Approval: July 8, 2020

CRITERIA FOR PRIOR AUTHORIZATION

Migraine Prophylaxis Agents

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Table 1 below.

Eptinezumab (Vyepti™)
Erenumab-aooe (Aimovig™)
Fremanezumab-vfrm (Ajovy™)
Galcanezumab-gnlm (Emgality™)
OnabotulinumtoxinA (Botox®)
Topiramate extended-release (Qudexy XR®, Trokendi XR®)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- For all agents listed, the preferred PDL drug, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Medication must be prescribed by or in consultation with a neurologist.
- Patient has a diagnosis of chronic migraines or episodic migraines.[1]
    - **Chronic migraine:** 15 or more headache days per month, lasting 4 hours a day or longer, for more than three months, which, on at least 8 days/month, has the features of migraine headache.
    - **Episodic migraine:** 4 to 14 migraine days per month.
- Patient must have experienced an inadequate response after a trial (at least 90 days) of at least one agent from each medication class listed in **Table 2** at a maximum tolerated dose, OR have a documented intolerance or contraindication to all preventive therapies.[2,6]
    - Prescriber must provide details of all previous medication trials. Documentation must include the medication name(s), trial date(s) and outcome(s) of the trial (i.e. inadequate response, intolerance or contraindication).
- For **Botulinum toxin** or **CGRP antagonist:**
    - The patient must **NOT** be on concurrent combination of botulinum toxin and CGRP antagonist.
    - If switching between botulinum toxin or CGRP antagonist:
        - At least 90 days must have elapsed after last treatment with botulinum toxin.
        - At least 30 days must have elapsed after last treatment with a CGRP antagonist.
- For **topiramate ER (Qudexy XR®, Trokendi XR®)**:
    - Prescriber must provide compelling rationale of why the patient will benefit from topiramate ER over topiramate IR. Note: adherence and/or convenience are not an accepted rationale.

LENGTH OF APPROVAL (INITIAL): 6 months

APPROVED PA Criteria

CRITERIA FOR RENEWAL: (must meet all of the following)

- Dose must not exceed limit in Table 1.
- The patient has experienced a reduction in the number of monthly headache days of at least moderate severity compared to baseline (prior to starting treatment with the requested agent).
- Re-initiation, if reverting from other step therapies, must meet one of the following:
    - Must not have had a botulinum toxin treatment for chronic migraine in the past 90 days.
    - Must discontinue CGRP antagonists for at least 30 days from last dispensing (90 days from last dispensing if quarterly dosing was used).

LENGTH OF APPROVAL (RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 1. FDA-approved age and dosing limits for Migraine Prophylaxis Agents.[6-12]

Agents	Indication(s)	Age	Dosing Limits
Anticonvulsants			
Topiramate ER (Qudexy XR®, Trokendi XR®)**	Migraine prophylaxis*	≥12 years	100 mg orally once daily.
Botulinum Toxins			
OnabotulinumtoxinA (Botox®)	Chronic migraine prophylaxis	≥18 years	155 units IM every 12 weeks.
Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists			
Eptinezumab-jjmr (Vyepti™)	Chronic migraine prophylaxis	≥18 years	300 mg IV every month.
Erenumab-aooe (Aimovig™)	Migraine prophylaxis*	≥18 years	70mg to 140mg SC once monthly. If using 140mg, must use the package labeled specifically for 40mg/mL.
Fremanezumab-vfrm (Ajovy™)	Migraine prophylaxis*	≥18 years	Either 225 mg (1.5 mL/1 syringe) SC per month OR 675 mg SC (4.5 mL/3 syringes) every 3 months.
Galcanezumab-gnlm (Emgality™)**	Migraine prophylaxis*	≥18 years	240 mg (2 mL/2 syringes) SC for initial dose and 120 mg (1 mL/1 syringe) SC for maintenance dosing.

SC: subcutaneously, IV: intravenously

*Migraine prophylaxis refers to both episodic and chronic migraine types, as defined above.

**For other indications not listed, see the statement above Table 1.

Table 2. Prior Preventative Migraine Therapies.[3]

Beta-blocking Agents	Antiepileptic Agents
Metoprolol	Divalproex (sodium)
Propranolol***	Topiramate***
Timolol	Valproate (sodium)

***Medications with established efficacy in pediatric patients include topiramate and propranolol.[4,5]

APPROVED PA Criteria
Notes:

OnabotulinumtoxinA	Safety and effectiveness of Botox have not been established for prophylaxis of episodic migraine (14 headache days or fewer per month).[6]
Topiramate ER	Titrate for migraine prophylaxis according to the following schedule: Week 1: 25mg once daily, Week 2: 50mg once daily, Week 3: 75mg once daily, Week 4: 100mg once daily.[11,12] The clinical studies used in the approval of the FDA indication of migraines occurred prior to the definition of chronic migraines, which was officially described by ICHD version 2 that was published in 2004.

References

1. Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders,3rd edition. Cephalalgia. 2018;38:1-211. Available at https://ichd-3.org/.
2. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Neurology 2016; 86 (19): 1818-26. Available at https://www.aan.com/Guidelines/home/GuidelineDetail/735.
3. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Neurology 2012; 78:1337-45. Available at https://n.neurology.org/content/78/17/1337.
4. Practice guideline update summary: Pharmacologic treatment for pediatric migraine prevention. Neurology 2019;93:500–509. Available at https://n.neurology.org/content/93/11/500.
5. Headaches in over 12s: diagnosis and management. Updated Feb 2020. Available at: https://www.nice.org.uk/guidance/cg150. Accessed 6/5/20.
6. Botox (onabotulinumtoxinA) [package insert]. Madison, NJ: Allergan USA, Inc.; October 2019.
7. Vyepti (eptinezumab) [prescribing information]. Bothell, WA: Lundbeck Seattle BioPharmaceuticals Inc; February 2020.
8. Aimovig (erenumab-aooe) [package insert]. Thousand Oaks, CA: Amgen Inc.; Mar 2019.
9. Ajovy (fremanezumab-vfrm) [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; Sep 2018.
10. Emgality (galcanezumab-gnlm) [package insert]. Indianapolis, IN: Eli Lilly and Company; Jun 2019.
11. Qudexy XR (topiramate) extended-release capsules [prescribing information]. Maple Grove, MN: Upsher-Smith Laboratories, LLC; February 2020.
12. Trokendi XR (topiramate) extended-release capsules [prescribing information]. Rockville, MD: Supernus Pharmaceuticals; February 2019.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

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