SmartPA Criteria Proposal

Drug/Drug Class:	Calcitonin Gene-Related Peptide (CGRP) Inhibitors PDL Edit
First Implementation Date:	July 11, 2019
Proposed Date:	December 16, 2021
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state specific preferred drug list.

Why Issue Selected: Migraine headache is a chronic, debilitating condition that tends to afflict young, productive, and otherwise healthy people. Patients with frequent or severe migraine headaches who are refractory to acute treatments should receive preventative therapy. Calcitonin gene-related peptide (CGRP) mediates trigeminovascular pain from intracranial vessels to the central nervous system. Stimulation of the trigeminal ganglion induces the release of CGRP, and CGRP infusion can trigger a migraine attack. CGRP inhibitors bind to the CGRP receptor and antagonize CGRP receptor function.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Ajovy® • Emgality® 120 mg/mL	• Aimovig® • Emgality® 100 mg/mL • Vyepti®

Type of Criteria: ☐ **Increased risk of ADE** ☒ **Preferred Drug List**
☒ **Appropriate Indications** ☐ **Clinical Edit**

Data Sources: ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Calcitonin Gene-Related Peptide (CGRP) Inhibitors
- Age range: All appropriate MO Healthnet participants 18 years of age or older

Approval Criteria

- Participant aged 18 years or older **AND**
- For Aimovig, Ajovy, Emgality 120 mg/mL, or Vypeti
  - Documented diagnosis of chronic or episodic migraine **AND**

- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents
- For first fill only:
  - History of ≥ 4 migraines per month **AND**
  - Adequate therapeutic trial of 2 prophylactic options from 2 different categories including:
    - Anticonvulsants: divalproex, valproate, topiramate
    - Antidepressants: amitriptyline, venlafaxine
    - Beta blockers: atenolol, metoprolol, nadolol, propranolol, timolol
  - Authorization is for 3 months only
- ~~**For renewal following first 3 months of therapy only: reduction in migraines by 2 or more per month from baseline**~~

- For Emgality 100 mg/mL
  - Documented diagnosis of episodic cluster headache **AND**
  - Therapeutic trial of verapamil AND topiramate (60/90 days for each) required on first fill only

Denial Criteria

- For diagnosis of chronic or episodic migraine on the first fill only: Botox therapy in the past 90 days
- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitations on the following:

Drug Description	Generic Equivalent	Max Dosing Limitations
AIMOVIG SURECLICK 70 MG/ML AUTOINJECTOR	ERENUMAB	1 autoinjector per 20 days
AIMOVIG SURECLICK 140 MG/ML AUTOINJECTOR	ERENUMAB	1 autoinjector per 20 days
AJOVY 225 MG/1.5 ML AUTOINJECTOR	FREMANEZUMAB	3 autoinjectors per 76 days
AJOVY 225 MG/1.5 ML SYRINGE	FREMANEZUMAB	3 syringes per 76 days
EMGALITY 100 MG/ML SYRINGE	GALCANEZUMAB	3 syringes per 20 days
VYEPTI 100 MG/ML VIAL	EPTINEZUMAB-JJMR	3 vials per 76 days

Required Documentation

Laboratory Results:		Progress Notes:	X
MedWatch Form:		Other:	

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

6 months

References

- Evidence-Based Medicine and Fiscal Analysis: “Calcitonin Gene-Related Peptide Receptor Blockers – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; November 2021.
- Evidence-Based Medicine Analysis: “Calcitonin Gene-Related Peptide (CGRP) Inhibitors”, UMKC-DIC; September 2021.
- USPDI, Micromedex; 2021.
- Drug Facts and Comparisons On-line; 2021.