Criteria Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Galcanezumab-gnlm (Emgality)

**Initial approval criteria:** Non-formulary galcanezumab-gnlm (Emgality) will be covered for 4 months on the prescription drug benefit when the following criteria are met:

- Prescribed by neurology provider with expertise in diagnosing/treating headache **AND**
- Patient is between the ages of 18 and 65 years old **AND**
- Prescribed for treatment of chronic migraine or episodic migraine **AND**
- Patient does not have history of cluster headache or hemiplegic migraine **AND**
- Documented adequate trial (2 or more months) with treatment failure, or inadequate response to 3 preventative agents for migraine, 2 of which must include: a tricyclic antidepressant (amitriptyline or nortriptyline), or a beta-blocker (metoprolol or propranolol), or topiramate, or valproate; or patient has intolerance or contraindication **AND**
- If patient has used OnabotulinumtoxinA (Botox) injection for migraine treatment, last injection was greater than or equal to 8 weeks ago **AND**
- If prescribed opiates or barbiturate products, patient is using 4 days or less in the month prior to initiation **AND**
- If prescribed triptan or ergotamine products, patient is using less than 10 days per month **AND**
- Patient does not have cardiac comorbidities [eg uncontrolled hypertension, history of myocardial infarction (MI), stroke, transient ischemic attack (TIA), unstable angina, coronary artery bypass surgery] **AND**
- Patient does not have abnormal blood vessels of the brain (eg arteriovenous malformation, aneurysm, arterial dissection, reversible cerebral vasoconstriction) **AND**
- Patient does not have history of thrombotic event **AND**
- Patient does not have alanine transaminase (ALT) greater than 1.5 times upper limit of normal or known liver disease

**Continued use criteria (after 3 months of treatment):** Non-formulary galcanezumab-gnlm (Emgality) will continue to be covered for 12 months on the prescription drug benefit when the following criteria are met:

- Prescribed by neurology provider with expertise in diagnosing/treating headache **AND**
- Prescribed for treatment of chronic migraine or episodic migraine **AND**
- 30% or more reduction in headache days per month (via headache diary) **OR** 50% or more improvement in MIDAS scores after 3 months of treatment **AND**
- If prescribed opiates or barbiturate products, patient is using 4 days or less in the month prior to initiation **AND**
- If prescribed triptan or ergotamine products, patient is using less than 10 days per month **AND**
- Patient does not have cardiac comorbidities [eg uncontrolled hypertension, history of myocardial infarction (MI), stroke, transient ischemic attack (TIA), unstable angina, coronary artery bypass surgery] **AND**
- Patient does not have history of thrombotic event **AND**
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Galcanezumab-gnlm (Emgality)

- Patient does not have alanine transaminase (ALT) greater than 1.5 times upper limit of normal or known liver disease

**Continued use criteria for stable members:** Non-formulary galcanezumab-gnlm (Emgality) will continue to be covered for 12 months on the prescription drug benefit when the following criteria are met:

- Prescribed by neurology provider with expertise in diagnosing/treating headache AND
- Prescribed for treatment of chronic migraine or episodic migraine AND
- Documented adequate trial (2 or more months) with treatment failure, or inadequate response to 3 preventative agents for migraine, 2 of which must include: a TCA (amitriptyline or nortriptyline), or a beta-blocker (metoprolol or propranolol), or topiramate, or valproate; or patient has intolerance or contraindication AND
- Patient does not have cardiac comorbidities [eg uncontrolled hypertension, history of myocardial infarction (MI), stroke, transient ischemic attack (TIA), unstable angina, coronary artery bypass surgery] AND
- Patient does not have abnormal blood vessels of the brain (eg arteriovenous malformation, aneurysm, arterial dissection, reversible cerebral vasoconstriction) AND
- Patient does not have history of thrombotic event AND
- Patient does not have alanine transaminase (ALT) greater than 1.5 times upper limit of normal or known liver disease