Sample Letter: Brekiya autoinjector – Letter of Medical Necessity for cluster headaches

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[Insurance Company]
[Address Line 1]
[Address Line 2]

Re: Patient Name: _____
Policy ID: _____
Policy Group: _____
Date of Birth: _____

[Date]

Attn: [Medical/Pharmacy Director], [Department]

Re: Letter of Medical Necessity for Brekiya® (dihydroergotamine mesylate) injection for [Plan Member Name]

Dear [Medical/Pharmacy Director or Appeals Department],

I am writing on behalf of my patient, [patient's name], who has been diagnosed with cluster headache. Based on my clinical experience, I request approval for my patient to receive Brekiya based on medical necessity.

[Patient's name] is a [patient's age]-year-old [male/female]. I most recently saw [patient's name] on [date of visit]. Based on the patient's symptoms and history of medication use (as outlined below), it is medically necessary for them to undergo treatment with Brekiya.

Brekiya is dihydroergotamine mesylate (DHE) indicated for the acute treatment of cluster headaches in adults. Brekiya is bioequivalent to subcutaneous D.H.E. 45®.[1] Brekiya is an autoinjector for at-home administration.[2]

Brekiya is necessary at this time for the following reasons:

- Sustained headache relief (approximately 24-72 hours)[3]
  - In a study of 54 adult cluster headache patients admitted to the hospital on 64 occasions, 93% of episodic cluster patients remained completely headache free 3 months after IV DHE administration
- Brekiya is one of only 4 drugs that is FDA-approved for cluster headache[1,2]
- Brekiya is the only form of DHE available as an autoinjector, with no assembly, priming the device, or refrigeration required. Since patients with cluster headache experience severe pain and eye swelling/drooping eyelid, or excessive tearing during attacks, the uncomplicated and straightforward administration process will benefit the patient and ensure they receive a full dose of medication[1,2,4]

Patient's Clinical History:
Diagnosis:
☐ Acute Cluster Headache (ICD-10: G44.009)
☐ Other: [Diagnosis and ICD-10 code]

Previous Treatment History:

Medication	Dose	Outcome
[Medication]	[Dose]	Ineffective / Not tolerated
[Medication]	[Dose]	Ineffective / Not tolerated
[Medication]	[Dose]	Ineffective / Not tolerated

[Patient Name] has not responded adequately to other treatments and cannot use triptans due to [e.g., non-response/efficacy, adverse reactions]. Given this history, Brekiya is both clinically appropriate and medically necessary.

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In summary, it is my professional judgment that it is medically necessary for [patient's name] to receive Brekiya. Based on [his/her/their] clinical needs, Brekiya is vital to their treatment.

Please contact my office at [office phone number] if any additional information is required to ensure prompt approval for this course of treatment. Thank you for your serious consideration of this important medical necessity.

Sincerely,
[Your Name, Credentials]
[Your Practice/Institution Name]
[NPI Number]
[Reminder to list enclosures as appropriate: clinical documentation, original denial letter, treatment and medication history, full prescribing information (available at www.brekiya.com)]

References: 1. Data on file, Amneal Pharmaceuticals LLC. **2.** Brekiya [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; 2025. **3.** Mather PJ, Silberstein SD, Schulman EA, Hopkins MM. *Headache.* 1991;31(8):525-532. doi:10.1111/j.1526-4610.1991.hed3108525.x4 **4.** Mayo Clinic. Cluster Headache. https://www.mayoclinic.org/diseases-conditions/cluster-headache/symptoms-causes/syc-20352080. Updated August 26, 2023. Accessed June 26, 2025.

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