Sample letter: Brekiya – Letter of Appeal for migraine with and without aura

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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: URGENT Letter of Appeal for Brekiya® (dihydroergotamine mesylate) injection for [Plan Member Name]

Dear [Medical/Pharmacy Director],

I am writing on behalf of my patient, [patient's name], who was denied coverage for Brekiya for the diagnosis of migraine. I ask for your urgent reconsideration of this decision.

[Patient's name] is a [patient's age]-year-old [male/female] patient, who has a diagnosis of migraine. 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. I am appealing this coverage decision, as I consider this medication critical to my patient's medical needs.

Brekiya is dihydroergotamine mesylate (DHE) indicated for the acute treatment of migraine with or without aura in adults. Brekiya is bioequivalent to subcutaneous D.H.E. 45®, which although has been difficult to obtain due to consistent supply shortages over the years, has remained a mainstay for the acute treatment of migraine for decades.[1,2] Brekiya is an autoinjector for at-home administration.[3]

Brekiya is necessary at this time for the following reasons:

- Sustained headache relief (approximately 24-72 hours)[4]
    - In a randomized, double-blind trial of 295 adult patients with migraine with or without aura, experiencing moderate to severe head pain:
        - Significantly more patients experienced pain relief with subcutaneous D.H.E. 45® 24 hours post dose than subcutaneous sumatriptan (90% vs 77%) (*P*=0.004)
        - Of those, 82% achieved pain freedom in the D.H.E. 45® group vs 70% in the sumatriptan group
        - More than 8 in 10 patients taking subcutaneous D.H.E. 45® had no headache recurrence within 24 hours post-dose. Headache recurrence was defined as an increase in pain severity from none or mild at least 2 hours after achieving pain relief.
- Brekiya can be used at any point during an attack, beneficial for patients who delay dosing due to nausea and/or vomiting, and can reverse central sensitization[3,5]
    - Clinical studies of DHE have shown that it is effective in treating patients with acute migraine with or without aura, rapid-onset migraine, migraine upon awakening, status migrainosis, medication overuse headache, or patients who do not respond to triptans or gepants[2,3,6-9]

- Brekiya is the only form of DHE available as an autoinjector, with no assembly, priming the device, or refrigeration required. Since patients may experience migraine-associated cognitive dysfunction or visual disturbances during attacks, the uncomplicated and straightforward administration process will benefit the patient and ensure they receive a full dose of medication[1,3]

Patient's Clinical History:
Diagnosis:

☐ Migraine with aura (ICD-10: G43.109)
☐ Migraine without aura (ICD-10: G43.909)
☐ 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 first-line therapies and/or cannot use triptans due to [e.g., non-response/efficacy, adverse reactions, contraindications, poor tolerability]. [Oral gepants/ditans have also produced suboptimal relief or adverse events]. Given this history, Brekiya is both clinically appropriate and medically necessary.

In summary, I am asking you to reconsider approving Brekiya for [patient's name], as I have concluded that it is critical to my patient's medical needs. Based on [his/her/their] clinical needs, Brekiya is vital to their treatment.

[A copy of the denial letter is included along with medical notes in response to the denial.]

Please contact my office at [office phone number] if any additional information is required to ensure approval of this appeal.

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

References: 1. Data on file, Amneal Pharmaceuticals LLC. **2.** Silberstein SD, Shrewsbury SB, Hoekman J. *Headache*. 2020;60(1):40-57. doi:10.1111/head.13700. **3.** Brekiya [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; 2025. **4.** Winner P, Ricalde O, Le Force B, Saper J, Margul B. *Arch Neurol*. 1996;53(2):180-184. doi:10.1001/archneur.1996.00550020092020 **5.** Burstein R, Jakubowski M, Rauch SD. *J Vestib Res*. 2011; 21(6):305-314. doi:10.3233/VES-2012-0433. **6.** Silberstein SD, Kori SH. *CNS Drugs*. 2013;27(5):385-394. doi:10.1007/s40263-013-0061-2. **7**. Shafqat R, Flores-Montanez Y, Delbono V, Nahas SJ. *J Pain Res*. 2020;13:859-864. doi:10.2147/JPR.S203650. **8**. Tepper SJ, Albrecht D, Kellerman D. *Cephalalgia Reports*. 2024;7. doi:10.1177/25158163241292297 **9**. Tepper SJ. *Headache*. 2013; 53. doi:10.1111/head.12184

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