[PRESCRIBER ADDRESS BLOCK]

[Date]

[INSURANCE ADDRESS BLOCK]

Insured Individual: Policy Holder Last Name, Policy Holder First Name

Relationship to Patient:

Policy Number:

Group Number:

To Whom It May Concern:

I am writing you on behalf of my patient, *Patient Name*, to provide information about EPIDIOLEX® (cannabidiol) and request reimbursement for this medication. EPIDIOLEX® must remain consistently accessible and efficiently processed by payors and specialty pharmacies as uncontrolled epilepsy is associated with profoundly decreased outcomes in patients with tuberous sclerosis complex (TSC). *Patient Name* has been under my care since *date* for the treatment and management of TSC.

It is my understanding that *Patient Name’s* plan does not cover EPIDIOLEX® for the treatment of seizures associated with tuberous sclerosis complex as of writing this letter. However, it is in my professional opinion as *Patient Name’s* specialist that it is medically necessary due to *patient’s pronoun* recurrent seizures.

TSC is a rare genetic neurocutaneous syndrome that can affect multiple organ systems. It is an autosomal dominant disorder caused by pathogenic variants in either the *TSC1* or *TSC2* gene, leading to the formation of nonmalignant tumors and cysts affecting the brain, lungs, kidneys, hearts, eyes, and skin.[[1]](#footnote-1) TSC affects approximately 1 in 6,000 live births, two-thirds of which arise from *de novo* mutations.[[2]](#footnote-2) 85% of people with TSC experience seizures, of which more than 50% have intractable epilepsy.[[3]](#footnote-3) Quality of life is usually most impacted by the neurological manifestations of TSC particularly during childhood and adolescence. These symptoms include seizures and intractable epilepsy, learning disorders, and cognitive impairment.

The TSC community has invested time and resources into furthering research into cannabidiol and EPIDIOLEX®, including participation in a phase III double-blinded, randomized controlled trial. Data from this trial, GWPCARE6 ([NCT02544763](https://clinicaltrials.gov/ct2/show/NCT02544763))[[4]](#footnote-4) and its subsequent open-label extension ([NCT02544750](https://clinicaltrials.gov/ct2/show/NCT02544750)), show EPIDIOLEX® was “well-tolerated in patients with TSC” and “reductions in seizures were maintained through 48 weeks with a high proportion of patients reporting global improvement.”[[5]](#footnote-5)

On July 31, 2020 the Food and Drug Administration (FDA) approved a third indication for EPIDIOLEX® for the treatment of seizures associated with tuberous sclerosis complex in patients aged 1 and older.[[6]](#footnote-6) EPIDIOLEX® is also indicated for the treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome for the same age range of patients.

[OPTIONAL: EXTRA MATERIALS]

I am including with this letter the following documentation to assist and expedite your coverage decision:

* *Previous and current anti-epileptic therapies used by your patient and why they were discontinued (efficacy or tolerability)*
* *Pertinent recent laboratory or diagnostic tests, such as: EEG, MRI, genetic testing, liver function tests*
* *Other supporting documents/medical records to substantiate why this would be the next logical step in your medical judgment to help the patient achieve better seizure reduction*

Based on the clinical data and recent FDA indication addition, I request your approval of EPIDIOLEX® as appropriate and medically necessary for my patient. If any further information is necessary of this request, please contact me at *phone number* to discuss.

Thank you for your attention to this request.

Sincerely,

Prescriber Name

1. <https://ghr.nlm.nih.gov/condition/tuberous-sclerosis-complex#definition> [↑](#footnote-ref-1)
2. Krueger, D. A., Northrup, H., & Tuberous, I. (2013). *Pediatric Neurology.* Tuberous Sclerosis Complex Surveillance and Management: Recommendations of the 2012 International Tuberous Sclerosis Complex Consensus Conference q. 49. https://doi.org/10.1016/j.pediatrneurol.2013.08.002 [↑](#footnote-ref-2)
3. Chu-Shore, C. J., Major, P., Camposano, S., Muzykewicz, D., & Thiele, E. A. (2010). The natural history of epilepsy in tuberous sclerosis complex. *Epilepsia*, 51(7), 1236–1241. <https://doi.org/10.1111/j.1528-1167.2009.02474.x> [↑](#footnote-ref-3)
4. Thiele E, Wong M. Cannabidiol (CBD) treatment in patients with seizures associated with tuberous sclerosis complex: a randomized, double-blind, placebo-controlled phase 3 trial (GWPCARE6). Presented at: AES 2019; December 7–10; Baltimore, Maryland. Abstract 1.293. <https://www.aesnet.org/meetings_events/annual_meeting_abstracts/view/2421288> [↑](#footnote-ref-4)
5. Thiele, E., Bebin, E. M, et al. (2020). Long-term Safety and Efficacy of Cannabidiol (CBD) for the Treatment of Seizures in Patients with Tuberous Sclerosis Complex (TSC) in an Open-label Extension (OLE) Trial (GWPCARE6) (677). *Neurology*, 94(15 Supplement), 677. Retrieved from <http://n.neurology.org/content/94/15_Supplement/677.abstract> [↑](#footnote-ref-5)
6. <https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/210365s005s006s007lbl.pdf> [↑](#footnote-ref-6)