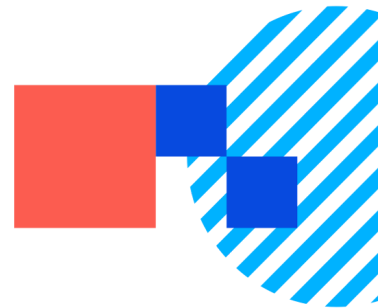




Vigabatrin Prior Authorization

Drug Applied:	vigabatrin
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Criteria:

Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Therapy Criteria

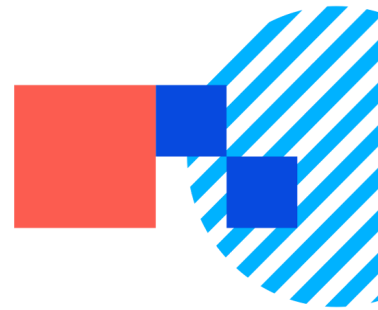
A. Refractory complex partial seizures as indicated by chart notes within past 120 days

1. Patient has tried and had an inadequate response to 3 or more antiseizure medications from different classes at maximally tolerated doses **and**
2. Vigabatrin will be used as an adjunctive therapy **and**
3. ONE of the following
 - a) Chart notes and/or prescriber provide documentation of baseline vision assessment
 - b) Chart notes and/or prescriber provide documentation of vision assessment exemption (e.g. patient is blind) **and**
4. Prescriber is a specialist in the area of the patient's diagnosis (e.g., neurology or epileptologist)

Approval Duration: 3 months

B. Infantile spasms as indicated by chart notes within past 90 days

1. Patient has a documented diagnosis of infantile spasms confirmed by an electroencephalogram (EEG) demonstrating hypsarrhythmia, modified hypsarrhythmia, or other diagnostic epileptic encephalopathy features **and**
2. Patient is less than 24 months of age **and**
3. ONE of the following
 - a) Patient has tried and had an inadequate response or intolerance to glucocorticoids (e.g. prednisolone) or has a contraindication to glucocorticoids
 - b) Patient has tried and had an inadequate response to adrenocorticotrophic hormone (ACTH) (i.e. Acthar Gel)
 - c) Vigabatrin will be used in combination with prednisolone or ACTH **and**
4. Provider has documented the potential benefits of the requested agent outweigh the potential risk of vision loss **and**
5. Prescriber is a specialist in the area of the patient's diagnosis (e.g., neurology or



epileptologist)

Approval Duration: 4 weeks

II. Continued Therapy Criteria

A. Refractory complex partial seizures as indicated by chart notes within past 6 months months

1. Patient meets the initial therapy criteria above **and**
2. Documented substantial clinical benefit since starting the requested agent (i.e., less seizures) **and**
3. ONE of the following
 - a) Chart notes and/or prescriber provide documentation of repeat vision assessment within past 3 months
 - b) Chart notes and/or prescriber documentation of vision assessment exemption (e.g. patient is blind) **and**
4. Prescriber is a specialist in the area of the patient's diagnosis (e.g., neurology or epileptologist)

Approval Duration: 12 months

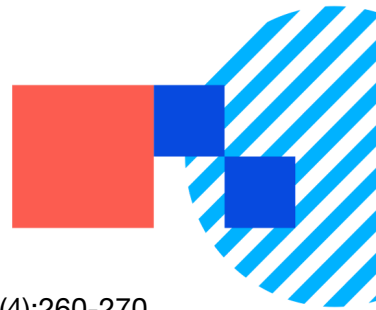
B. Infantile spasms as indicated by chart notes within past 90 days

1. Patient meets the initial therapy criteria above **and**
2. Patient is less than 24 months of age **and**
3. Documented substantial clinical benefit since starting the requested agent (i.e., less seizures) **and**
4. Provider has documented the potential benefits of the requested agent outweigh the potential risk of vision loss **and**
5. Prescriber is a specialist in the area of the patient's diagnosis (e.g., neurology or epileptologist)

Approval Duration: 3 months

References:

1. Vigabatrin prescribing information. Actavis Pharma, Inc. October 2021.
2. Vigabatrin Risk Evaluation and Mitigation Strategy (REMS). <https://www.vigabatrinrems.com/>
3. Bresnahan, R., Gianatsi, M., Maguire, M. J., Tudur Smith, C., & Marson, A. G. (2020). Vigabatrin add-on therapy for drug-resistant focal epilepsy. *The Cochrane database of systematic reviews*, 7(7), CD007302. <https://doi.org/10.1002/14651858.CD007302.pub3>.
4. Boonkrongsak, R., Trongkamolchai, K., Suwannachote, S., Sri-Udomkajorn, S., Wittawassamrankul, R., Arya, R., & Sakpichaisakul, K. (2025). Combination Therapy With Vigabatrin and Prednisolone Versus Vigabatrin Alone for Infantile Spasms. *Annals of clinical and translational neurology*, 12(5), 1012–1021. <https://doi.org/10.1002/acn3.70034>.



5. Nelson, Gary Rex. [Management of Infantile Spasms](#). Transl Pediatr. 2015;4(4):260-270.
6. Ramantani, G, Bolsterli, B, Alber, M, et al. [Treatment of Infantile Spasm Syndrome: Update from the Interdisciplinary Guideline Committee Coordinated by the German-Speaking Society of Neuropediatrics](#). Neuropediatrics. 2022 Sep 22;53(6):389–401.
7. Desnoux B, Lenoir M, Bitton JY, et al. [What is the optimal duration for vigabatrin monotherapy in patients with infantile spasms: 6 months or longer?](#) Seizure. 2021 Oct; 91:503-506.

Policy Owned by: Curative PBM team