BlueCross BlueShield
Federal Employee Program

SABRIL, **VIGADRONE**, VIGAFYDE (**vigabatrin**)

Preferred products: Vigadrone and vigabatrin

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Although its complete mechanism of action is unknown, the anti-epileptic drug (AED) vigabatrin targets the enzyme GABA-transferase (GABA-T), which breaks down the central nervous neurotransmitter GABA. Limiting the action of GABA-T helps to increase levels of GABA and potentially lessen frequency of seizures of the complex partial type that have been refractory to prior therapies. Vigabatrin also treats infantile spasms in children 2 years of age or under (1-3).

Regulatory Status

FDA-approved indications: Vigabatrin is an antiepileptic drug (AED) indicated for (1-3):

1. Refractory complex partial seizures – Sabril/Vigadrone are indicated in patients 2 years of age or older. It should be used as adjunctive therapy in patients who have responded inadequately to several alternative treatments.
2. Infantile Spasms - monotherapy in infants 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.

<u>Off-Label Use:</u>

Refractory complex partial seizures in patients 3-9 years of age:

The majority of patients included in the original clinical trials that evaluated the use of vigabatrin for the treatment of refractory partial seizures were adults, and therefore efficacy and safety had not been established in this age group at that time. However, further studies conducted have demonstrated that the use of vigabatrin is effective in decreasing seizure frequency in this population of pediatric patients compared with baseline (4-5).

Vigabatrin may cause temporary or permanent vision symptoms, including double vision and blurring, and has boxed warnings for vision loss that may continue after ending therapy; including possible permanent loss. Patients, prescribers, and pharmacies must all be enrolled in Vigabatrin REMS program. For patients receiving Vigabatrin, vision assessment is recommended at baseline (no later than 4 weeks after starting therapy), at least every 3 months while on therapy, and about 3-6 months after the discontinuation of therapy. Similar to other AEDs, vigabatrin also increases the risk of depression and suicide; patients should be monitored for mood or behavior changes (1-

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3).

Summary

Vigabatrin is an anti-epileptic drug that targets the enzyme, GABA-transferase (GABA-T) which breaks down the central nervous neurotransmitter GABA. Limiting the action of GABA-T helps to increase levels of GABA and potentially lessen frequency of seizures; it also treats infantile spasms. Vigabatrin has boxed warnings for the risk of vision loss, possibly permanent, in some cases (1-3).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of vigabatrin while maintaining optimal therapeutic outcomes.

References

1. Sabril [package insert]. Deerfield, IL: Lundbeck; October 2021.
2. Vigadrone [package insert]. Maple Grove, MC: Upsher-Smith Laboratories, LLC; March 2023.
3. Vigafyde [package insert]. Parsippany, NJ: Pyros Pharmaceuticals, Inc. June 2024.
4. Greiner HM, Lynch ER et al. Vigabatrin for childhood partial-onset epilepsies. Pediatric Neurology 2012; 46:83 – 88.
5. Nielsen JC, Dwain T, et al. Vigabatrin pediatric dosing information for refractory complex partial seizures: results from a population dose-response analysis. Epilepsia, 55(12):e134–e138, 2014.