RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Although its complete mechanism of action is unknown, the anti-epileptic drug (AED) Sabril/Vigadrone 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. Sabril/Vigadrone also treats infantile spasms in children 2 years of age or under (1-2).

Regulatory Status
FDA-approved indications: Sabril/Vigadrone is an antiepileptic drug (AED) indicated for (1-2):

1. Refractory complex partial seizures - in patients 10 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.

Off-label Use:
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 (3-4).

Sabril/Vigadrone 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 SHARE REMS program. All patients should have a baseline vision check and be periodically monitored for both visual field and acuity. Similar to other AEDs, Sabril/Vigadrone also increases the risk of depression and suicide; patients should be monitored for mood or behavior changes (1-2).
Summary
Sabril/Vigadrone 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. Sabril/Vigadrone has boxed warnings for the risk of vision loss, possibly permanent, in some cases (1-2).

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

References