OVERVIEW

FDA-APPROVED INDICATIONS
Sabril is an antiepileptic drug (AED) indicated for:
- Refractory Complex Partial Seizures in patients ≥10 years of age. It should be used as adjunctive therapy in patients who have responded inadequately to several alternative treatments.
- Infantile Spasms as monotherapy in infants 1 month to 2 years of age.

PHARMACY COVERAGE GUIDELINES
Tufts Health Plan – Network Health may authorize coverage of Sabril (vigabatrin) for members when ALL of the following criteria are met and limitations do not apply:

Infantile spasms
1. The member has been evaluated by a neurologist AND
2. The member is between the ages of 1 month and 2 years of age with a diagnosis of Infantile Spasms AND
3. The member’s baseline vision been assessed by an ophthalmologist or the member’s vision will be assessed within 4 weeks of initiating Sabril therapy OR
4. The member is blind or has been formally exempt from vision assessment in the SHARE program.

Refractory Complex Partial Seizures
1. The member has been evaluated by a neurologist AND
2. The member is 17 years of age or older with a diagnosis of refractory complex partial seizures AND
3. The member has tried and failed at least 2 antiepileptic medications for complex partial seizures such as carbamazepine, gabapentin, lamotrigine, levetiracetam, oxcarbazepine, topiramate, valproic acid, divalproex sodium, zonisamide or tiagabine AND
4. Sabril will be used in combination with at least one other antiepileptic medication AND
5. The member’s baseline vision been assessed by an ophthalmologist or the member’s vision will be assessed within 4 weeks of initiating Sabril therapy OR
6. The member is blind or has been formally exempt from vision assessment in the SHARE program.

LIMITATIONS
1. Initial authorization for infantile spasm will be limited to 8 weeks up to 150 mg/kg/day. Subsequent authorization may be given to extend until the member is 2 years of age, not to exceed 2 grams per day, based on submission of current progress notes from the physician documenting efficacy.

2. Initial authorization for the treatment of refractory complex partial seizures will be limited to 4 months up to 3 grams per day or up to 6 grams per day if the member is new to Tufts Health Plan – Network Health and has been stable on doses greater than 3 grams per day prior to enrollment or the provider indicates that a lower dose is now associated with decreased efficacy. Subsequent authorizations may be given in 12-months intervals, up to 6 grams per day, based on submission of current progress notes from the physician documenting efficacy.

CODES
None
REFERENCES

APPROVAL HISTORY
- April 12, 2012: Reviewed by the Pharmacy and Therapeutics Committee.
- November 4, 2014: Reviewed by the Pharmacy and Therapeutics Committee.

BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION
Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request Guidelines are developed for selected therapeutic classes or drugs found to be safe but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to all insured offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines, when applicable, and adherence to plan policies and procedures and claims editing logic.