DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Antiseizure Medications – Vigabatrin Drug Quantity Management Policy – Per Rx

- Sabril® (vigabatrin tablets and powder for oral solution – Lundbeck, generic)
- Vigadrone® (vigabatrin tablets and powder for oral solution – Upsher-Smith [generic to Sabril powder for oral solution])
- Vigafyde™ (vigabatrin solution – Pyros)
- Vigpoder™ (vigabatrin powder for oral solution – Pyros [generic to Sabril powder for oral solution])

REVIEW DATE: 02/04/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Sabril (generic), Vigadrone (generic), and Vigpoder (generic), antiseizure medications, are indicated for the following uses:[1,2,5,6]

- **Refractory complex partial seizures** as adjunctive therapy in adults and pediatric patients ≥ 2 years of age who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss. Vigabatrin is not indicated as a first line agent for complex partial seizures.

- **Infantile spasms** as monotherapy in pediatric patients 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.

Vigafyde is indicated for **infantile spasms** as monotherapy in pediatric patients 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.[4]

Dosing and Administration

Vigabatrin's dosing regimen depends on the indication, age group, weight, and dosage form (i.e., tablets or powder for oral solution).[1] Patients with impaired renal function require dose adjustment. Vigabatrin may be taken with or without food. Vigabatrin powder for oral solution should be mixed with water prior to administration. A calibrated measuring device is recommended to measure and deliver the prescribed dose accurately. A household teaspoon or tablespoon is not an adequate measuring device. Each individual dose should be prepared and used immediately. Discard any unused portion of the solution after administering the correct dose. When discontinuing vigabatrin, the dose should be gradually reduced.

Refractory Complex Partial Seizures

Adults (Patients ≥ 17 Years of Age)

Treatment with vigabatrin should be initiated at 1,000 mg per day (500 mg twice daily [BID]).[1,2,6] Total daily dose may be increased in 500 mg increments at weekly intervals, depending on response. The recommended dose of vigabatrin in adults is 3,000 mg per day (1,500 mg BID). However, doses up to 6,000 mg per day have been studied.[1,3] According to current guidelines, vigabatrin doses of 1, 3, and 6 grams per day yielded significant higher responder rates and larger reductions in monthly seizure frequency.[3] Fatigue and drowsiness are the most frequent adverse events, with higher drug discontinuation in the 6 gram per day group.

Pediatric (Patients 2 to 16 Years of Age)

The recommended dosage of vigabatrin is based on body weight and administered as two divided doses.[1,2,6] The dosage may be increased in weekly intervals to the total daily maintenance dosage, depending on response (Table 1). Pediatric patients weighing > 60 kg should be dosed according to adult recommendations.

Table 1: Dosing Recommendations for Vigabatrin in Pediatric Patients Weighing 10 kg up to 60 kg.[1]

Body Weight	Recommended Total Daily Maintenance Dose
10 kg to 15 kg	1,050 mg/day
> 15 kg to 20 kg	1,300 mg/day
> 20 kg to 25 kg	1,500 mg/day
> 25 kg to 60 kg	2,000 mg/day

Infantile Spasms (patients 1 month to 2 years of age)

The initial daily dosage of vigabatrin is 25 mg/kg BID (50 mg/kg/day); subsequent dosing can be titrated by 25 mg/kg/day to 50 mg/kg/day increments every 3 days,

up to a maximum of 75 mg/kg BID (150 mg/kg/day).[1,2,4,5] See Table 2 for dosing for vigabatrin 500 mg powder packet products (Sabril [generic], Vigadrone [generic], and Vigpoder [generic]).[1] Table 3 presents dosing for Vigafyde (100 mg/ml vigabatrin solution).[4]

Table 2: Dose and Volume of Vigabatrin 500 mg Powder Packets in Infants by Weight.[1]

Infant Weight	Starting Dose 50 mg/kg/day		Maximum Dose 150 mg/kg/day	
3 kg	75 mg BID	One packet BID	225 mg BID	One packet BID
4 kg	100 mg BID		300 mg BID	
5 kg	125 mg BID		375 mg BID	
6 kg	150 mg BID		450 mg BID	
7 kg	175 mg BID		525 mg BID	Two packets BID
8 kg	200 mg BID		600 mg BID	
9 kg	225 mg BID		675 mg BID	
10 kg	250 mg BID		750 mg BID	
11 kg	275 mg BID		825 mg BID	
12 kg	300 mg BID		900 mg BID	
13 kg	325 mg BID		975 mg BID	
14 kg	350 mg BID		1,050 mg BID	Three packets BID
15 kg	375 mg BID		1,125 mg BID	
16 kg	400 mg BID		1,200 mg BID	

BID – Twice daily.

Table 3: Dose and Volume of Vigafyde 100 mg/mL Solution in Infants by Weight.[4]

Infant Weight	Starting Dose 50 mg/kg/day		Maximum Dose 150 mg/kg/day	
3 kg	75 mg BID	0.75 mL BID	225 mg BID	2.25 mL BID
4 kg	100 mg BID	1 mL BID	300 mg BID	3 mL BID
5 kg	125 mg BID	1.25 mL BID	375 mg BID	3.75 mL BID
6 kg	150 mg BID	1.5 mL BID	450 mg BID	4.5 mL BID
7 kg	175 mg BID	1.75 mL BID	525 mg BID	5.25 mL BID
8 kg	200 mg BID	2 mL BID	600 mg BID	6 mL BID
9 kg	225 mg BID	2.25 mL BID	675 mg BID	6.75 mL BID
10 kg	250 mg BID	2.5 mL BID	750 mg BID	7.5 mL BID
11 kg	275 mg BID	2.75 mL BID	825 mg BID	8.25 mL BID
12 kg	300 mg BID	3 mL BID	900 mg BID	9 mL BID
13 kg	325 mg BID	3.25 mL BID	975 mg BID	9.75 mL BID
14 kg	350 mg BID	3.5 mL BID	1,050 mg BID	10.5 mL BID
15 kg	375 mg BID	3.755 mL BID	1,125 mg BID	11.25 mL BID
16 kg	400 mg BID	4 mL BID	1,200 mg BID	12 mL BID

BID – Twice daily.

Availability

Vigabatrin (Sabril, generic) and Vigadrone are available as 500 mg film-coated tablets, scored on one side and supplied in bottles of 100 tablets.[1,6] Vigabatrin (Sabril, generic), Vigadrone, and Vigpoder are available as powder for oral solution in 500 mg packets of powder and supplied in cartons of 50 packets.[1,2,5] Vigafyde is available as 100 mg/mL oral solution in a 150 mL bottle.[4]

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of vigabatrin. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity Per Rx	Home Delivery Maximum Quantity Per Rx
Sabril® (vigabatrin tablets and powder for oral solution, generic)	500 mg tablets	180 tablets	540 tablets
	500 mg powder packets	200 packets*	550 packets*
Vigadrone® (vigabatrin powder for oral solution)	500 mg tablets	180 tablets	540 tablets
	500 mg powder packets	200 packets*	550 packets*
Vigpoder™ (vigabatrin powder for oral solution)	500 mg powder packets	200 packets*	550 packets*
Vigafyde™ (vigabatrin oral solution)	100 mg/mL (150 mL bottles)	5 bottles (750 mL)	15 bottles (2,250 mL)

* Quantity limits allow for the patient to discard any unused portion of the packet after administering the correct dose. A new packet(s) should be used at each daily dose.

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

Vigabatrin (Sabril, generic) and Vigadrone 500 mg tablets

1. If a patient requires a dose of more than 3,000 mg per day, approve the requested quantity not to exceed 360 tablets per dispensing at retail or 1,080 tablets per dispensing at home delivery.
Note: This override allows for dosing up to 6,000 mg per day.

Vigabatrin (Sabril, generic), Vigadrone, and Vigpoder 500 mg powder packets

1. If a patient requires a dose of more than 3,000 mg per day, approve the requested quantity not to exceed 400 packets per dispensing at retail or 1,100 packets per dispensing at home delivery.
Note: This override allows for dosing up to approximately 6,000 mg per day, rounded to the nearest 50 packet carton.

Vigafyde 100 mg/mL solution

1. If a patient requires a dose of more than 2,500 mg per day, approve the requested quantity not to exceed 15 bottles (2,250 mL) per dispensing at retail or 45 bottles (6,750 mL) per dispensing at home delivery.
Note: This override allows for dosing up to approximately 6,000 mg per day, rounded to the nearest 150 mL bottle.

REFERENCES

1. Sabril® tablets and powder packets [prescribing information]. Deerfield, IL: Lundbeck; October 2021.
2. Vigadrone® powder packets [prescribing information]. Maple Grove, MN: Upsher-Smith; July 2025.
3. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: efficacy and tolerability of the new antiepileptic drugs II: treatment-resistant epilepsy: report of the guideline development, dissemination, and implementation subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology*. 2018;91(2):82-90.
4. Vigafyde™ solution [prescribing information]. Parsippany, NJ: Pyros. September 2025.
5. Vigpoder™ solution [prescribing information]. Parsippany, NJ: Pyros. July 2023.
6. Vigadrone® tablets [prescribing information]. Maple Grove, MN: Upsher-Smith; March 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Vigpoder 500 mg powder packets**: Vigpoder 500 mg powder packets were added to the policy. The same quantity limits and clinical overrides apply to Vigpoder as apply to vigabatrin 500 mg powder packets (Sabril, generic).	01/24/2024
Annual Revision	**Vigafyde 100 mg/mL oral solution**: Vigafyde 100 mg/mL oral solution was added to the policy. Quantity limits of 5 bottles (750 mL) at retail and 15 bottles (2,250 mL) at home delivery were added. Override criteria was added to allow for the maximum dose of 6,000 mg per day.	02/05/2025
Annual Revision	**Vigpoder 500 mg tablets:** Vigpoder 500 mg tablets were added to the policy. The same quantity limits and clinical overrides apply to Vigpoder tablets as apply to vigabatrin 500 mg tablets (Sabril, generic). **Vigabatrin (Sabril, generic), Vigadrone, and Vigpoder 500 mg powder packets:** Standard quantity limits were updated to 200 packets per dispensing at retail (previously 150 packets) and 550 packets per dispensing at home delivery (previously 450 packets). The override criteria was updated such that if the dose exceeds 3,000 mg per day, a clinical override will provide for a quantity up to 400 packets per dispensing at retail (previously 350 packets) and 1,100 packets per dispensing at home delivery (previously 1,050 packets). These limits were updated to reflect the requirement to dose whole packets and discard remainder, and to dispense in full cartons.	02/04/2026