Clinical Policy: Brivaracetam (Briviact)

Reference Number: CP.PCH.26
Effective Date: 05.21.19
Last Review Date: 08.23
Line of Business: Commercial, HIM

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Brivaracetam (Briviact®) is an anticonvulsant.

FDA Approved Indication(s)

Briviact is indicated for the treatment of partial-onset seizures in patients 1 month of age and older.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Briviact is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Partial-Onset Seizure (must meet all)**:**

1. Diagnosis of partial-onset seizure;
2. Age ≥ 1 month;
3. Failure of two preferred agents* for partial-onset seizures *(see Appendix B),* unless clinically significant adverse effects are experienced or all are contraindicated;
   **May require prior authorization.*
4. If request is for intravenous (IV) Briviact, oral Briviact administration is temporarily not feasible (e.g., status epilepticus, reliance on gastrostomy tube, recent oral or neck surgery, esophageal condition or intraoral infection, myasthenia gravis or other neuromuscular condition);
5. Documentation of member's current weight, for dose calculation purposes;
6. Dose does not exceed any of the following (a-d):
   a. For adults and pediatric members weighing ≥ 50 kg (i and ii):
      i. 200 mg per day;
      ii. One of the following (1 or 2):
         1) 2 tablets per day;
         2) 20 mL per day;
   b. For pediatric members weighing 20 kg to < 50 kg: 4 mg/kg per day;
   c. For pediatric members weighing 11 kg to < 20 kg: 5 mg/kg per day;
   d. For pediatric members weighing < 11 kg: 6 mg/kg per day.

Approval duration: 12 months (oral formulation); 1 month (IV formulation)

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.33 for health insurance marketplace; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.103 for health insurance marketplace; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace.

II. Continued Therapy

A. Partial-Onset Seizure (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Briviact for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for intravenous (IV) Briviact, oral Briviact administration is temporarily not feasible (e.g., status epilepticus, reliance on gastrostomy tube, recent oral or neck surgery, esophageal condition or intraoral infection, myasthenia gravis or other neuromuscular condition);
4. Documentation of member's current weight, for dose calculation purposes;
5. Dose does not exceed any of the following (a-d):
   a. For adults and pediatric members weighing ≥ 50 kg (i and ii):
      i. 200 mg per day;
      ii. One of the following (1 or 2):
         1) 2 tablets per day;
         2) 20 mL per day;
   b. For pediatric members weighing 20 kg to < 50 kg: 4 mg/kg per day;
   c. For pediatric members weighing 11 kg to < 20 kg: 5 mg/kg per day;
   d. For pediatric members weighing < 11 kg: 6 mg/kg per day.

Approval duration: 12 months (oral formulation); 1 month (IV formulation)

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.33 for health insurance marketplace; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.103 for health insurance marketplace; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial or HIM.PA.154 for health insurance marketplace, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

IV: intravenous

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Preferred drugs for partial-onset seizures: carbamazepine (Carbatrol®, Equetro®, Tegretol®, Tegretol XR®) clonazepam (Klonopin®) ethosuximide (Zarontin®) gabapentin (Neurontin®) lamotrigine (Lamictal®, Lamictal® ODT) levetiracetam (Keppra®, Keppra XR®) oxcarbazepine (Trileptal®) phenobarbital phenytoin (Dilantin®, Dilantin Infatabs®, Phenytek®) pregabalin (Lyrica®) primidone (Mysoline®) tiagabine (Gabitril®) topiramate (Topamax®, Topamax® Sprinkle) valproate (Depakene®, Depacon, Depakote®, Depakote® ER) Vimpat® (lacosamide) zonisamide (Zonegran®)	See full prescribing information	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to brivaracetam or any of the inactive ingredients in Briviact
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose

Monotherapy or adjunctive therapy	**Adults (age ≥ 16 years):**
	• Initial dosage: 50 mg PO or IV BID (100 mg/day)
	• Maintenance dosage: 25 mg to 100 mg PO or IV BID (50 to 200 mg/day; based on individual tolerability, therapeutic response)
	Pediatrics (age ≥ 1 month):
	• Weight ≥ 50 kg
	  ○ Initial dosage: 25 mg to 50 mg PO or IV BID (50 mg to 100 mg/day)
	  ○ Maintenance dosage: 25 mg to 100 mg PO or IV BID (50 to 200 mg/day; based on individual tolerability, therapeutic response)
	• Weight 20 kg to < 50 kg
	  ○ Initial dosage: 0.5 mg/kg to 1 mg/kg PO or IV BID (1 mg/kg to 2 mg/kg per day)
	  ○ Maintenance dosage: 0.5 mg/kg to 2 mg/kg PO or IV BID (1 mg/kg to 4 mg/kg per day; based on individual tolerability, therapeutic response)
	• Weight 11 kg to < 20 kg
	  ○ Initial dosage: 0.5 mg/kg to 1.25 mg/kg PO or IV BID (1 mg/kg to 2.5 mg/kg per day)
	  ○ Maintenance dosage: 0.5 mg/kg to 2.5 mg/kg PO or IV BID (1 mg/kg to 5 mg/kg per day; based on individual tolerability, therapeutic response)
	• Weight < 11 kg
	  ○ Initial dosage: 0.75 mg/kg to 1.5 mg/kg PO or IV BID (1.5 mg/kg to 3 mg/kg per day)
	  ○ Maintenance dosage: 0.75 mg/kg to 3 mg/kg PO or IV BID (1.5 mg/kg to 6 mg/kg per day; based on individual tolerability, therapeutic response)
		200 mg/day

VI. Product Availability

- Tablets: 10 mg, 25 mg, 50 mg, 75 mg, 100 mg
- Oral solution: 10 mg/mL (300 mL)
- Injection: 50 mg/5 mL (5 mL)

VII. References

1. Briviact Prescribing Information. Smyrna, GA: UCB, Inc.; May 2023. Available at https://www.briviact.com/briviact-PI.pdf. Accessed May 18, 2023.
2. Andres M. Kanner, MD, Eric Ashman, MD, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new-onset epilepsy. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Neurology 2018;91:74-81. doi:10.1212/WNL.0000000000005755.
3. Andres M. Kanner, MD, Eric Ashman, MD, 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;91:82-90. doi:10.1212/WNL.0000000000005756.
4. Epilepsies: diagnosis and management. National Institute for Health and Care Excellence (NICE) website. https://www.nice.org.uk/guidance/CG137/chapter/Appendix-E-Pharmacological-treatment. Updated April 2018.
5. Glauser T, Ben-Menachem E, Bourgeois B. Special report: Updated ILAE evidence review of antiepileptic drug efficacy and effectiveness as initial monotherapy for epileptic seizures and syndromes. Epilepsia, 2013; 54(3):551-563.
6. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/. Accessed May 12, 2022.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
C9399, J3490	Injection, brivaracetam

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	05.21.19	08.19
3Q 2020 annual review: added Commercial line of business to the policy; for HIM, increased initial authorization duration from 6 months to 12 months to align with other oral anticonvulsant policies; removed neurologist prescriber requirement to align with other oral AED policies for partial-onset seizures; references reviewed and updated.	05.04.20	08.20
3Q 2021 annual review: no significant changes; revised HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	04.19.21	08.21
RT4: updated criteria for pediatric extension to 1+ month of age and dosing in section V.	09.20.21	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2022 annual review: no significant changes; added a requirement for documentation of member's current weight, for dose calculation purposes; references reviewed and updated.	05.12.22	08.22
Template changes applied to other diagnoses/indications.	09.29.22	
3Q 2023 annual review: no significant changes; for continuation of therapy of IV Briviact, added requirement for documentation that the oral formulation is temporarily not feasible, just as is required upon initial approval; references reviewed and updated.	05.18.23	08.23

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to

recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.