Preemptive policy: This is a P&T approved policy and can be used after the drug is FDA approved until it is superseded by an updated policy

CENTENE® Corporation

Clinical Policy: Troriluzole (BHV-4157)

Reference Number: CP.PHAR.639
Effective Date: FDA Approval Date
Last Review Date: 05.25
Line of Business: Commercial, HIM, Medicaid

Revision Log

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

Description

Troriluzole (BHV-4157) is a glutamate-modulating agent.

FDA Approved Indication(s) [Pending]

BHV-4157 is indicated for the treatment of spinocerebellar ataxia (SCA).

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 BHV-4157 is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. Spinocerebellar Ataxia (must meet all)**:**

1. Confirmed genotypic diagnosis of one of the following SCA genotypes: 1, 2, 3, 6, 7, 8, or 10;*
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 18 years;*
4. Baseline modified functional Scale for the Assessment and Rating of Ataxia (f-SARA) score meets all of the following (a, b, and c):*
   a. Total score ≥ 3;
   b. Gait subsection score ≥ 1;
   c. For each individual item of the scale, score < 4;
5. Mini-Mental State Examination (MMSE) score ≥ 24;*
6. Member is able to ambulate ≥ 8 meters without human assistance (canes and other devices are allowed);*
7. BHV-4157 is not prescribed concurrently with riluzole;*
8. Dose does not exceed 200 mg per day.*

Approval duration: 12 months

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, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; 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, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; 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, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. Spinocerebellar Ataxia (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy;*
3. If request is for a dose increase, new dose does not exceed 200 mg per day.*

Approval duration: 12 months

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, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; 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, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; 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, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
f-SARA: modified functional Scale for the Assessment and Rating of Ataxia
SCA: spinocerebellar ataxia

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings [Pending]
- Contraindication(s): pending
- Boxed warning(s): pending

Appendix D: General Information
- Troriluzole is a tripeptide prodrug of the active metabolite, riluzole.

V. Dosage and Administration [Pending]

Indication	Dosing Regimen	Maximum Dose
SCA*	200 mg PO QD*	200 mg/day*

VI. Product Availability [Pending]
Pending

VII. References

1. Biohaven Pharmaceuticals, Inc. Troriluzole in adult subjects with spinocerebellar ataxia. Available at: https://clinicaltrials.gov/ct2/show/NCT03701399. Accessed March 12, 2025.
2. Biohaven Pharmaceuticals, Inc. Real-world data study of troriluzole-treated patients with spinocerebellar ataxia (SCA) compared to a matched natural history control. Available at: https://clinicaltrials.gov/study/NCT06529146. Accessed March 12, 2025.
3. Biohaven Pharmaceuticals, Inc. Biohaven provides update on phase 3 clinical trial evaluating troriluzole for spinocerebellar ataxia (SCA). Press release published May 23, 2022. Available at: https://www.prnewswire.com/news-releases/biohaven-provides-update-on-phase-3-clinical-trial-evaluating-troriluzole-for-spinocerebellar-ataxia-sca-301552633.html. Accessed March 12, 2025.

4. Biohaven Pharmaceuticals, Inc. Biohaven achieves positive topline results in pivotal study of troriluzole in spinocerebellar ataxia (SCA). Press release published September 23, 2024. Available at: https://ir.biohaven.com/news-releases/news-release-details/biohaven-achieves-positive-topline-results-pivotal-study. Accessed March 12, 2025.
5. Biohaven Pharmaceuticals, Inc. Biohaven announces FDA acceptance and priority review of troriluzole new drug application for the treatment of spinocerebellar ataxia. Press release published February 11, 2025. Available at: https://ir.biohaven.com/news-releases/news-release-details/biohaven-announces-fda-acceptance-and-priority-review. Accessed March 12, 2025.
6. National Institute of Neurological Disorders and Stroke. Spinocerebellar ataxias including Machado-Joseph disease. Available at: https://www.ninds.nih.gov/health-information/disorders/spinocerebellar-ataxias-including-machado-joseph-disease. Last reviewed July 19, 2024. Accessed March 12, 2025.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively.	06.14.23	08.23
Policy retired due to FDA refusal to file the submitted NDA for SCA3.	05.08.24	08.24
Policy recreated due to FDA acceptance of new NDA for SCA: expanded diagnosis to include additional genotypes SCA1, SCA2, SCA6, SCA7, SCA8, and SCA10 based on new data.	03.12.25	05.25

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.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.