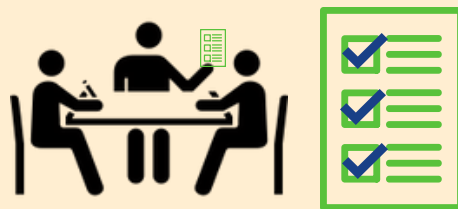


EXPANDED ACCESS PROTOCOL FOR ALS BHV0223-401 FDA Reviewed, IRB Approved Information for Physicians

If you are interested in participating in the Expanded Access Program for BHV-0223, contact Early Access Care at:
BHV0223.ExpandedAccess@earlyaccesscare.com or call 1-888-315-5797
(Option 6)

Eligibility Checklist & CDA

- Once contacted, Early Access Care will send the physician an Eligibility Checklist to ensure the patient meets all criteria for the Expanded Access Program (EAP).
- If the patient qualifies as eligible for the EAP, Early Access Care will customize a Confidentiality Disclosure Agreement (CDA) to be signed by the physician prior to receiving the protocol and other essential documents



Protocol to IRB

- The physician submits the protocol and informed consent to an Investigational Review Board (IRB) for approval. Although the EAP has IRB approval, the physician may still need to submit for review
- Once approved the physician will discuss the patient's eligibility



Costs

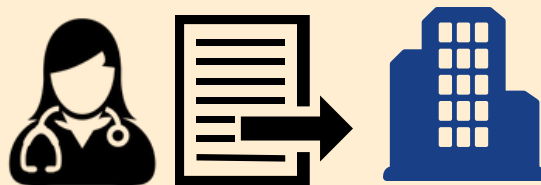
- Expanded Access for BHV-0223 is offered at no charge
- IRB fees are covered by Biohaven Pharma
- Potential hospital costs related to visits and safety monitoring may apply



Essential Documents

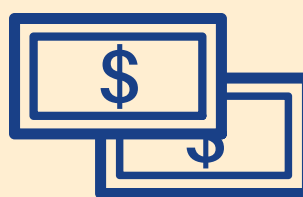
Upon receipt of the signed CDA, Early Access Care will forward the following essential documents:

- Protocol
- Form FDA 1572
- Informed Consent Form (ICF)
- Investigator's Brochure (IB)
- Site Contract



Informed Consent

- The physician will inform the patient on known and potential risks of BHV-0223 and any procedures that are required to monitor patient progress. This is called informed consent.



Logistics

- Early Access Care will ensure that BHV-0223 is shipped to the physician in the most expedient manner
- Patients will receive their shipment of BHV-0223 at the clinic/hospital. Drug will be taken at home, dosed every 12 hours

