Infant Botulism FAQ

For Healthcare Providers

West Virginia Department of HEALTH
BUREAU FOR PUBLIC HEALTH

This document provides guidance to healthcare providers on botulism testing and ordering BabyBIG® treatment for botulism in patients 15 months old or younger.

Background

Infant botulism is a medical emergency and requires prompt treatment**.** The Infant Botulism Treatment and Prevention Program (IBTPP) at the California Department of Public Health provides no-cost clinical consultations for suspected cases of infant botulism and is the only avenue to secure BabyBIG® treatment for infant botulism. This clinical consultation service is available 24 hours a day, seven days a week. The IBTPP on-call physician will release BabyBIG® treatment for infant botulism if the patient's clinical findings indicate botulism. In West Virginia, Botulism is a Category 1 immediately notifiable condition under the Reportable Disease Rule, 64CSR7. Healthcare providers should report all suspected cases of infant botulism to the local health department serving the patient's county of residence IMMEDIATELY.

What is BabyBIG®?

BabyBIG®, Botulism Immune Globulin Intravenous (Human) (BIG-IV), is the U.S. Food and Drug Administration approved treatment for infant botulism types A and B consisting of human-derived anti-botulism toxin antibodies.

How do I order BabyBIG® treatment for infant botulism?

Healthcare providers must call the Infant Botulism Treatment and Prevention Program at (510) 231-7600 for case consultation to order BabyBIG® botulism treatment for patients 15 months old or younger. IBTPP physicians will release BabyBIG® treatment if the patient's clinical findings indicate botulism.

What information will I need to provide the IBTPP to receive BabyBIG® treatment?

Healthcare providers will need to:

(1) Provide demographic and clinical information including medical history, feeding history, environmental exposures, history of present illness, review of systems, physical exam with weight in kilograms, neurologic, and cranial nerve findings, as well as any relevant diagnostic findings.
(2) Send the patient's medical records and a facesheet to the IBTPP by secure fax to (916) 636-6242. List the 24/7 phone and fax number for the patient's ward and the hospital pharmacy on the fax cover sheet.
(3) Coordinate the completion of the Invoice and Purchase Agreement with the hospital pharmacy.

Laboratory testing has not confirmed botulism, should I still order/administer BabyBIG® botulism treatment?

Healthcare providers should base initial diagnosis and treatment decisions on clinical presentation and findings. Laboratory confirmation for botulism can take up to 12 weeks. Botulism is a medical emergency, and treatment should be administered as soon as possible, do not wait for laboratory confirmation to administer treatment. If specimen collection would delay the administration of BabyBIG®, do not delay treatment to obtain a specimen. Contact West Virginia Office of Laboratory Services Bioterrorism Response Section (WV OLS BT) for guidance.

Should I report suspected cases of infant botulism to the local health department (LHD) before calling the IBTPP?

To prevent treatment delays, healthcare providers should contact the IBTPP to order BabyBIG® treatment before reporting the case to the local health department. Healthcare providers should report the case to the local health department serving the patient's county of residence immediately after contacting the IBTPP for clinical consultation.

How do I coordinate patient testing for botulism?

Botulism testing is coordinated through the West Virginia Office of Laboratory Services Bioterrorism Response Section (WV OLS BT) and performed by the Centers for Disease Control and Prevention (CDC) laboratory. Healthcare providers should discuss botulism testing when they report the case to the local health department.

What does the hospital laboratory need to know about submitting samples for botulism testing at CDC?

Acceptable specimens

- 10g of raw stool collected in a sterile container (preferred), OR
- 0.5 - 1 g stool can be tested (minimally accepted amount), OR
- If the minimally accepted stool sample cannot be collected, an enema can be obtained using sterile non-bacteriostatic water.

Collection instructions:

- Specimens should be collected prior to the administration of BabyBIG®.
- Refrigerate promptly and maintain refrigeration at 2-8°C until shipping.

Required Submission Forms

Complete the WV OLS Bioterrorism Clinical Sample Submission Form and the CDC Specimen Submission Form (50.34) for specimen submission. (Detailed instructions will be provided when you call the WV OLS BT Section at (304) 205-8917.)

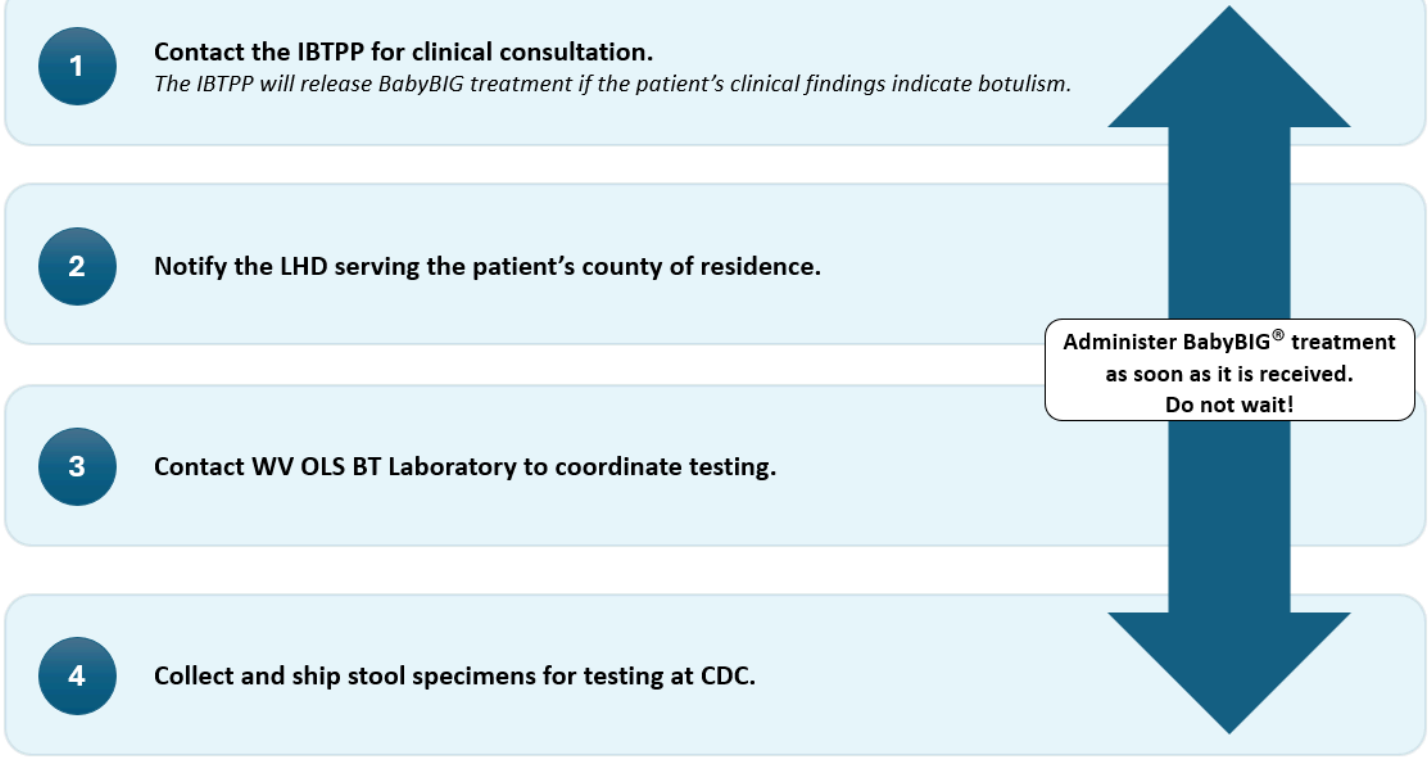
Shipping Considerations:

- Specimens must be shipped to CDC within two days of collection.
- CDC will not accept specimens on weekends or holidays. Ship specimens to arrive Monday through Friday.
- Pack on frozen cold packs, and label the box for biological hazards: UN3373 biological substance, Category B.
- Provide the FedEx tracking number and shipping date to the WV OLS and CDC points of contact.

Infant Botulism Immediate Contacts

- The Infant Botulism Treatment and Prevention Program (IBTPP): (510) 231-7600
- WV OLS BT Laboratory: (304) 205-8917
- Local health department: https://bph.wv.gov/media/56/download?inline
- Additional information: https://infantbotulism.org/

Summary Workflow for the Coordination of Infant Botulism Response Activities



Infant Botulism Checklist:

Coordinate BabyBIG® treatment with the IBTPP

1. Call the IBTPP physician on call **immediately** at (510) 231-7600 for a case consultation to secure the release of BabyBIG® treatment when you suspect a patient has infant botulism.
2. Send the patient's medical record to the IBTPP via secure fax.
3. Coordinate the completion of the IBTPP Invoice and Purchase Agreement with the hospital pharmacy.

Notify the Local Health Department

4. Report suspected cases of infant botulism to the local health department serving the patient's county of residence immediately after securing the release of BabyBIG® from the IBTPP.

Coordinate testing

5. Contact the WV OLS BT at (304) 205-8917 for botulism testing approval and instructions on specimen shipping.
6. Collect a stool sample for testing **before** administering BabyBIG® treatment if possible. Promptly refrigerate.
7. Complete WV OLS BT Clinical Sample Submission Form and the CDC 50.34 Submission Form.
8. Pack specimens on frozen cold packs.
9. Label the package for biological hazards: UN3373 biological substance, Category B.
10. Ship the specimen and CDC submission form to CDC within two days of collection. Arrange for the specimen to arrive Monday through Friday.
11. Email both specimen submission forms to the WV OLS BT Section at dholsbtlab@wv.gov.
12. Provide the FedEx tracking number and shipping date to the WV OLS BT and CDC points of contact.

Administer BabyBIG® treatment

13. Begin treatment with BabyBIG® as soon as possible. Do not wait to collect specimens or for laboratory confirmation.