

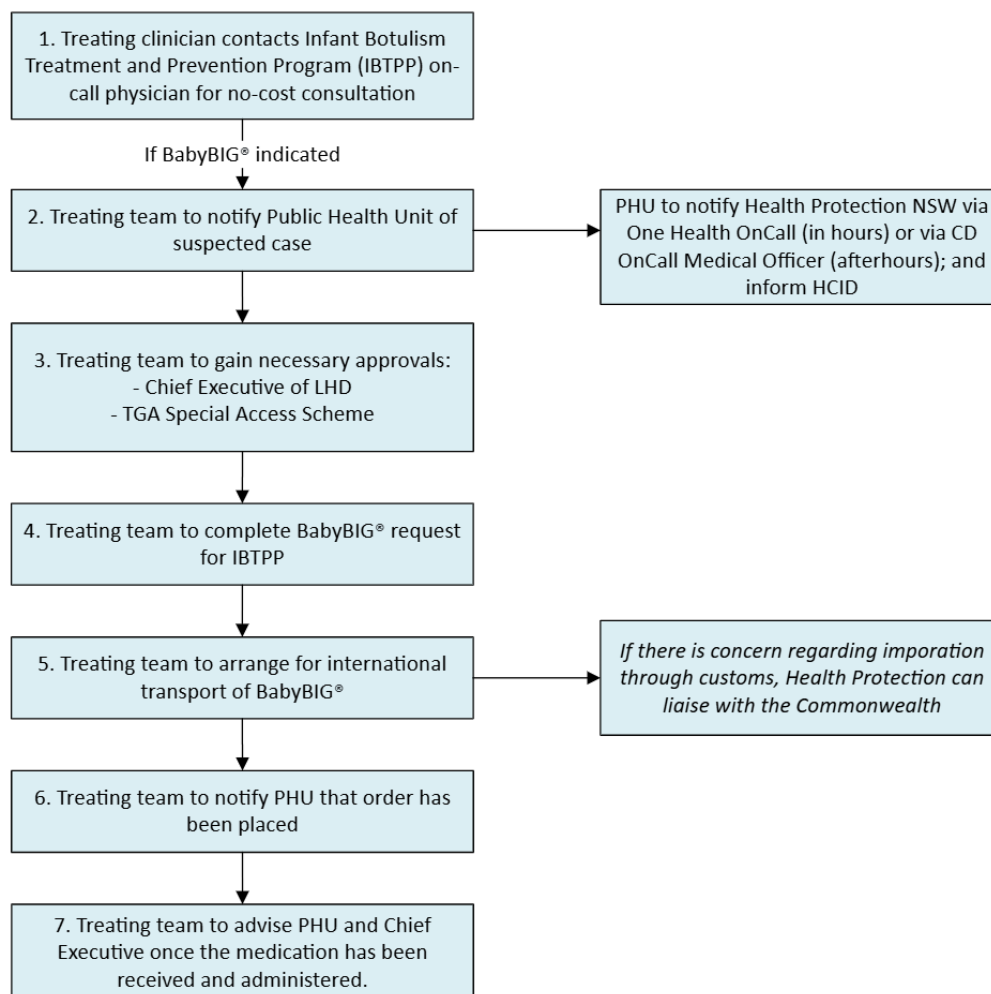
BabyBIG[®] Request Process

BabyBIG[®] is made and distributed by the California Department of Public Health
- www.infantbotulism.org

Note: This flowchart outlines the key steps in the request process; however, due to the rarity of BabyBIG[®] requests in NSW (and Australia more broadly), some steps may vary. The priority is to seek any necessary assistance to ensure timely access when clinically required.

If there are any issues in accessing BabyBIG at any step, this should be escalated to Health Protection NSW (HPNSW) in the first instance. HPNSW can liaise with the National Incident Centre as required.

Flowchart for acquiring BabyBIG[®]



Detailed steps for acquiring BabyBIG®

1. Clinical Decision for BabyBIG®

The decision to treat with BabyBIG® should be based on clinical presentation and findings and should **not** be delayed by waiting for results of laboratory confirmatory testing.

The treating clinician needs to contact the Infant Botulism Treatment and Prevention Program (IBTPP) on-call physician in California for a no-cost consultation to determine if BabyBIG® is indicated. This is a 24-hour service. Contact details and information regarding the consultation are available at

<https://www.infantbotulism.org/contact/international.php>

2. Notify Public Health of Suspected Infant Botulism

Suspected cases of infant botulism should be notified to the local Public Health Unit (PHU).

The PHU will notify Health Protection NSW via One Health OnCall (in-hours) or the CD OnCall Medical Officer (afterhours) of the suspected case. The PHU should also inform the NSW Specialist Service for High Consequence Infectious Diseases (HCID) via 1800 424 300, for awareness.

While the acquisition of BabyBIG® is the responsibility of the treating team, the PHU should provide support as needed. This includes sharing this process, directing the clinical team to the relevant website, and facilitating contact with the Health Protection NSW One Health Branch or the CD OnCall Medical Officer for any assistance they may be able to provide.

3. Approvals required for BabyBIG®

Local Executive Approval

Due to the cost associated with the purchase and transport of BabyBIG®, approval from the executive of the Local Health District (LHD) where the patient is admitted is required. While the cost is significant, this has not previously delayed timely acquisition. An Australian case study highlights both the long-term cost savings and the clear benefits of early recovery in affected infants - [Infant botulism in Australia: availability of human botulinum antitoxin for treatment](#)

TGA Special Access Scheme

TGA Special Access Scheme approval is required. This will be through the Category A pathway. This scheme is accessed through an online portal. Information about accessing the scheme can be found at <https://www.tga.gov.au/products/unapproved-therapeutic-goods/prescribe-unapproved-therapeutic-good-health-practitioners>

Once the form is completed, the PDF generated should be used as the *letter of authorization from the requesting country's Medicines Regulatory Authority or Agency* as this is a requirement of the IBTPP.

4. Complete BabyBIG® request through the IBTPP

Information on how to complete this request can be found at

<https://www.infantbotulism.org/contact/international.php>

5. Arrange for transport of BabyBIG®

Once ordered, a courier needs to be arranged for BabyBIG®. This should be arranged through the LHDs preferred courier service. This may involve working with LHD pharmacy services. Information on potential courier services is also provided at <https://www.infantbotulism.org/contact/international.php>.

It has previously taken approximately 36 – 48 hours for BabyBIG® to arrive.

6. Notify PHU that order has been placed

Confirm with the PHU that BabyBIG® has been ordered and provide details of the order. If there is concern about importation through customs, HPNSW One Health Branch (in hours) or the CD OnCall Medical Officer (afterhours) can liaise with the National Incident Centre to assess whether facilitation through customs is required.

7. Confirm receipt and administration of medication

Once medication has been received and administered, please advise your chief executive and the PHU.