



INVOICE and PURCHASE AGREEMENT for BabyBIG® (International)

Patient Name _____ **Invoice Number** _____
 (to be obtained from IBTPP)
Hospital Name _____ **Hospital P.O. Number** _____
 (if assigned, not required by CDPH)
City, State, Country _____ **Date** _____

Patient weight in kilograms at the time of order (# of vials needed is based on weight) _____

***** **INVOICE** *****

BabyBIG® FEE for the treatment of the above-named patient:..... **\$57,300--USD**

1. Name of Bank: **Bank of America, Sacramento, CA, USA**
2. Name of Account/Pay to: **CA Department of Public Health, BabyBIG® Fund 0272**
3. Bank Account Number: **14364-80640** (please use the dash)
4. Wire Transfer Instructions: **Wire Transfer payment ABA Number: 026009593**
SWIFT #: BOFAUS3N *We cannot accept checks; do not send a check.*
5. Invoice # _____ - **Deposit to BabyBIG® Fund 0272.**

Due Date: within five (5) business days from the date of this document as written above, in order to avoid liability for late penalties (see Terms and Payment, *Remedies for Breach*, paragraph 12)

INFORMATION and INSTRUCTIONS for Accounts Payable Department:

- Note that **this page is the invoice** for this order, a separate invoice will not be issued.
- If your facility is unable to wire funds directly, funds should be wired from your institution's regular bank.
- Remittance information must include the full invoice number/information as on line 5 above.

The payment information and account above shall be used exclusively for BabyBIG® fees. The IBTPP does not have a W-9 form distinct from CDPH; it is the responsibility of the Hospital/Purchaser to ensure that no vendor accounts are created in a manner that will result in inappropriate payments into the account listed above (e.g. payments for anything other than BabyBIG®).

If you have questions about this agreement and/or its invoice, please contact the CDPH/IBTPP at 1-510-231-7600.

GENERAL INSTRUCTIONS for PHARMACY to OBTAIN BabyBIG®

1. Using the invoice number issued by the **California Department of Public Health (CDPH)-Infant Botulism Treatment and Prevention Program (IBTPP)**, complete this form. If needed for your institution, obtain a Purchase Order number and enter it at the top of this page. A Purchase Order number is not required by CDPH/IBTPP to fulfill this order, it is for internal tracking purposes at the ordering facility. Once executed, this document is binding.
2. **Obtain the duly authorized institutional signatures on page 7 of this Agreement.** Make a copy of the signed Agreement (IPA) for your institution's Accounts Payable department.
Fax the completed IPA to the IBTPP at 1-916-636-6242 or 1-855-506-6566 (toll free). Shipment arrangements of the medicine to your hospital will begin after receipt of the signed agreement.
3. **Hand-deliver the copy of the IPA to your hospital's Accounts Payable department ASAP** for completing the wire transfer of funds.
4. Payment is required within five (5) business days.
5. Return the IPA with original signatures to IBTPP by postal mail, if possible (not required).
6. **Please note that your hospital is responsible for collecting and submitting a diagnostic stool/enema specimen(s)** (see Terms and Payment, *Request for BabyBIG®*).

PURCHASE AGREEMENT FOR BabyBIG®
[Botulism Immune Globulin Intravenous (Human)]

This Agreement (Agreement) is made and entered into this ____ day of _____, 20 ____ by and between the State of California, through its duly appointed, qualified and acting officer Katya Ledin, Ph.D., M.P.H., Chief, Infectious Diseases Laboratory Branch, California Department of Public Health, with a principal place of business located at 850 Marina Bay Parkway, Building E, Richmond, CA 94804, acting for the **California Department of Public Health Infant Botulism Treatment and Prevention Program**, which has its principal place of business located at **850 Marina Bay Parkway, Room E-361, Richmond, California 94804**, and the _____ (Hospital/Medical Center), with a principal place of business located at _____, hereafter called the Purchaser.

Recitals:

1. Whereas, in 1989 the California Department of Public Health (CDPH) in a Cooperative Agreement with the U.S. Food and Drug Administration (FDA) undertook the development and testing of Botulism Immune Globulin Intravenous (Human) (BIG-IV) for the treatment of the orphan disease of infant botulism; and,
2. Whereas, BIG-IV was designated by FDA in 1989 to be an Orphan Drug that is sponsored by CDPH; and,
3. Whereas, CDPH conducted a randomized, double-blinded, placebo-controlled, statewide pivotal clinical trial between 1992 and 1997, which demonstrated that BIG-IV is safe and effective for the treatment of infant botulism by reducing average hospital stay and average hospital costs by more than 55% each; and,
4. Whereas, on 23 October 2003 FDA licensed BIG-IV as BabyBIG® for the treatment of infant botulism types A and B; and,
5. Whereas, CDPH evaluated the efficacy and safety of BIG-IV in its first 12 years post-licensure 2003-2015 and determined that BIG-IV shortened average hospital stay from 5.7 weeks to 2.2 weeks and reduced average hospital costs from \$207,500 to \$118,600 (costs adjusted to 2015 dollars); and
6. Whereas, California Health & Safety Code Sections 123700-123709 established the Infant Botulism Treatment and Prevention Program (IBTPP) within CDPH for the purposes of a) assuring the on-going availability of a national supply of BabyBIG®, b) providing statewide diagnostic and nationwide consultative services for infant botulism, and c) reducing the occurrence of infant botulism and related illnesses in California; and,
7. Whereas, California Health & Safety Code Section 123704 requires the IBTPP to distribute BabyBIG® in California and nationwide to patients suspected of having infant botulism in accord with federal law; and,
8. Whereas, federal law authorizes and State law requires that CDPH as Sponsor of BabyBIG® charge a fee in exchange for BabyBIG® in order to meet but not exceed the IBTPP operational expenses, including the developmental and on-going production costs of BabyBIG®; and,
9. Whereas, State law mandates that IBTPP investigate ways to improve the treatment of infant botulism, including making technical improvements to BabyBIG®, and develop and implement control measures for the prevention of infant botulism and related illnesses; and,
10. Whereas, United States federal law [21 CFR 314.80(c)(2) and 21 CFR 314.81(b)(2)] requires CDPH as the

International Invoice and Purchase Agreement for BabyBIG®

Updated: April 2021

Sponsor of BabyBIG® to collect specified information, and federal law also authorizes hospitals to release patient "protected health information" without obtaining the subject's consent to the sponsor of a licensed medical product [45 CFR 164.512(b)(1)(iii)]; and,

11. Whereas, CDPH as the Sponsor of BabyBIG® is required to provide such information to FDA to comply with licensure maintenance requirements for BabyBIG®; and,

WHEREAS, _____ Hospital has admitted a patient whom it believes has infant botulism and wishes to procure BabyBIG® for the treatment of this patient;

NOW, THEREFORE, in consideration of the mutual covenants, conditions, agreements, and stipulations contained herein, and with the intent to be legally bound thereby, the parties do agree as follows:

Terms and Payment:

Method of Payment

1. a. Purchaser agrees to pay to CDPH/IBTPP in cash by **Wire Transfer only** a fee of \$57,300.00 USD (Fifty Seven Thousand Three Hundred Dollars) for the BabyBIG® needed to treat this patient.
 - b. **Purchaser agrees that the fee for BabyBIG® is the retail price for this product and agrees not to add any mark-ups to this price in order to collect fees in greater amounts when billing third parties for BabyBIG®.**
 - c. Payment must be received within **five (5) business days** of signing this agreement.
 - d. The **invoice number** for this transaction is _____.
(To be obtained from IBTPP)
 - e. The fee wire transfer instructions are as follows: a) Name of Bank: Bank of America, Sacramento, CA, b) Account Name: California Department of Public Health BabyBIG® Fund 0272, c) Bank Account Number: 14364-80640, and d) Wire-transfer ABA #: 026009593; SWIFT #BOFAUS3N
 - f. **Must include on transfer: "Deposit to _____ BabyBIG®/Fund 0272."**
(IBTPP Case #, obtain from IBTPP)
 - g. Hospital P.O. number, if assigned/known (optional): _____
- [For any difficulties encountered in using these instructions, please contact the CDPH/IBTPP at 1-510-231-7600 or CDPH Accounts Receivable at 1-916-322-1406]
2. Purchaser will pay shipment costs for sending appropriately packaged stool/enema specimen(s) to CDPH/IBTPP for testing or related confirmatory studies; and costs for returns of unused BabyBIG®, if any.

Request for BabyBIG®

3. Purchaser agrees to designate an attending staff physician for this patient. Purchaser shall require the attending staff physician to provide the following information to the IBTPP, as authorized by 45 CFR 164.512(b)(1)(iii):
 - a. Date and time of notification of public health officials of this case of possible infant botulism and of the specific arrangements made for diagnostic testing of fecal and/or enema specimen(s) for the mandatory establishment of the diagnosis of infant botulism, and
 - b. Additional information as specified in paragraphs 4, 5 and 6 of this Agreement to enable the IBTPP to investigate ways to improve the treatment of infant botulism.
4. Purchaser agrees to provide the following information and documents by electronic transfer (fax) at the time of its written request (i.e., the executed Invoice and Purchase Agreement) for BabyBIG®:
 - a. Name, address, telephone number and date of birth of the patient to be treated with BabyBIG®.
 - b. Name, address and telephone number of parent(s) or guardian(s) of the named patient.
 - c. Date(s) of admission to Purchaser's hospital and of admission to any hospital for the present illness that is considered to be probable infant botulism.
 - d. Admission diagnosis or diagnoses.
 - e. Hospital record number.
 - f. Name, address, business telephone and fax number of patient's attending physician.
 - g. Patient's admission history, physical examination findings, and results of laboratory and diagnostic studies.
 - h. Treatment plan and medications prescribed, or equivalent document.
5. Purchaser agrees to provide the following information to CDPH/IBTPP after administration of BabyBIG® to patient and within 24 hours of the occurrence or the recognition of occurrence:
 - a. Any adverse reaction in the patient treated with BabyBIG®, either suspected or actual, that occurs within five (5) days of administration of BabyBIG®.
 - b. The circumstances under which any adverse reaction, either suspected or actual, occurred within five (5) days of administration of BabyBIG®.
 - c. The reasons why the reaction may or may not have been related to the administration of BabyBIG®.
 - d. The transmission, or possible transmission, of any virus or other transmissible etiological agent to the patient due to administration of BabyBIG®.

6. Purchaser agrees to provide the following information at no charge to CDPH/IBTPP within two (2) weeks after the patient treated with BabyBIG[®] has been discharged from the hospital:
 - a. Admission and discharge summaries, and other medical record information if requested, e.g., nurses' notes, medication records, etc.
 - b. A listing of hospital charges, costs, and reimbursements for the patient's hospital stay.

Delivery of BabyBIG[®]

7. Upon receipt by facsimile (fax) of this executed Agreement by Purchaser, together with the information listed in Paragraph 4, CDPH/IBTPP agrees to provide and promptly ship to the Purchaser by an expedited courier known to CDPH to be qualified for this purpose the BabyBIG[®] needed to treat this patient. **For non-United States patients the shipping costs, handling fees, and customs charges for the delivery of BabyBIG[®] to the hospital are the responsibility of the Purchaser. Arrangements for billing of these charges must be made in advance of shipment. CDPH reserves the right to approve or disapprove any proposed alternative courier or third-party intermediary involved in the transport of BabyBIG[®] to the hospital.**

Liability

8. Purchaser shall be liable for loss or damage of BabyBIG[®] that occurs in transit or after transit subsequent to delivery of BabyBIG[®] to the transporting courier. BabyBIG[®] transfer of ownership from CDPH to Purchaser occurs when rehydration of the lyophilized product in the hospital pharmacy has begun.

Indemnification

9. Purchaser agrees to indemnify, defend and hold harmless the CDPH, its officers, agents, and employees from any and all liability, demands, claims, costs, losses, damages, recoveries, settlements, and expenses (including interest, penalties, attorney fees, accounting fees, and expert witness fees) incurred by Purchaser accruing or resulting to any person, firm or corporation who may be injured or damaged by the Purchaser as a result of Purchaser's action or inaction in the performance of this Agreement.
10. CDPH/IBTPP warrants that BabyBIG[®] will conform to the specifications and descriptions incorporated herein. **IBTPP MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, AND SPECIFICALLY MAKES NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OTHER THAN THE PURPOSES DETAILED IN THE SPECIFICATIONS AND DESCRIPTION IN THE U.S. FDA-APPROVED PACKAGE INSERT FOR BabyBIG[®].**

Remedies for Breach

11. All parties recognize and agree that information related to treatment with BabyBIG[®] and the rights and obligations set forth in this Agreement are unique and are of such a nature as to be inherently difficult or impossible to value monetarily. Therefore, in the event of a breach of this Agreement by any party, an action at law for damages or other remedies at law would be inadequate to protect the unique rights and interests of the parties to this Agreement. Accordingly, in any controversy concerning the purchase, sale, or shipment of BabyBIG[®] or of any of the terms of this Agreement, its provisions shall be enforceable by

specific performance. This remedy shall not be exclusive and shall be in addition to any other remedy available to the parties.

12. Purchaser acknowledges that IBTPP is relying on Purchaser to deliver the fee for BabyBIG[®] described in Paragraph 1 and the information described in Paragraphs 4, 5 and 6 within the time indicated in the terms of this Agreement. If Purchaser fails to deliver the fee or provide any item of information in accordance with the terms of this Agreement, Purchaser shall pay to IBTPP as liquidated damages and not as a penalty the amount of \$300.00 USD (Three Hundred Dollars) per day for each day delivery is delayed beyond the due date.

Miscellaneous

13. Without the written consent of the CDPH/IBTPP, this Agreement is not assignable by Purchaser either in whole or in part.
14. This Agreement constitutes a valid and binding obligation on each party, enforceable in accordance with its terms.
15. No consent or approval of any other person or governmental authority is necessary for this Agreement to be effective.
16. This Agreement constitutes the full understanding of the parties and a complete and exclusive statement of the terms of the Agreement.
17. This Agreement shall be governed by and construed in accordance with the laws of California.
18. Whenever possible, each provision of the Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of the Agreement shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of the Agreement.
19. No amendment of the terms of this Agreement shall be valid unless made in writing and signed by the parties hereto, and no oral understanding or agreement not incorporated herein, shall be binding on any of the parties hereto.

AUTHORIZED OFFICIAL OF THE HOSPITAL and PURCHASING INSTITUTION:
(International BabyBIG® Requests) Information required at the time of submission of this document.

Name of Patient's Hospital

Street Address

City, State or Province, Country

Signature of Hospital CFO or CEO/Date

Printed Name of Hospital CFO or CEO

Telephone # of Hospital CFO or CEO

Name and Telephone # of Pharmacy Contact

Institution Responsible for Payment

Signature of Authorized Official/Date

Printed Name/Title of Authorized Official

Address of Purchasing Institution
(if different than patient's hospital)

Email of Authorized Official

Telephone # of Authorized Official

Pharmacy License Number

Contact person in Accounts Payable Department of the Purchasing Institution to whom the Authorized Official will promptly deliver a copy of this Agreement:

Printed Name and Title of Accounts Payable Contact

Fax Number for Accounts Payable Contact

Phone Number for Accounts Payable Dept.

Email for Accounts Payable Contact

AUTHORIZED OFFICIAL OF THE CALIFORNIA DEPARTMENT OF PUBLIC HEALTH:



Katya Ledin, Ph.D., M.P.H., Chief
Infectious Diseases Laboratory Branch



Date