Proof Certificate

Resource Code: AINF-1176670-0004

Proof certified: Editorial proofread of PDF proof complete. .

	Signature
Nominated Editorial Signature:	Gilbert, Terrie (gilbeter) Digitally signed by Gilbert, Terrie (gilbeter) Date: 2018.11.14 12:38:23 -05'00'

The Merck Access Program
ENROLLMENT FORM

ZINPLAVA™ (bezlotoxumab) Injection 25 mg/mL

P: 877-709-4455 **F:** 800-977-1957
The Merck Access Program, PO Box 29067, Phoenix, AZ 85038

TO GET STARTED, COMPLETE THE ENROLLMENT FORM AND FAX IT TO 800-977-1957.
IF REQUESTING A REFERRAL TO THE MERCK PATIENT ASSISTANCE PROGRAM FOR ELIGIBILITY DETERMINATION (PROVIDED THROUGH THE MERCK PATIENT ASSISTANCE PROGRAM, INC.), PLEASE INCLUDE A PRESCRIPTION FOR *ZINPLAVA*.

PLEASE CHECK ALL THAT APPLY AND COMPLETE THE APPROPRIATE SECTION(S) OF THE FORM

○ **BENEFIT INVESTIGATION / PRIOR AUTHORIZATION / APPEAL**
If you wish to initiate a *Benefit Investigation* to understand the patient's insurance coverage for ZINPLAVA and/or obtain information about *Prior Authorizations* or *Appeals,* the enrolling physician or an authorized facility representative of the enrolling physician must **COMPLETE SECTIONS 1 THROUGH 5**

○ **MERCK CO-PAY ASSISTANCE PROGRAM**
Co-pay assistance is available for eligible privately insured patients who need help affording the out-of-pocket cost of the medication. Not all patients are eligible. Terms and Conditions apply. If the patient is seeking assistance from the Merck Co-Pay Assistance Program, the patient and his or her administering physician must **REVIEW AND COMPLETE SECTION 6 (ALONG WITH SECTIONS 1 THROUGH 5)**

○ **MERCK PATIENT ASSISTANCE PROGRAM**
If the patient is seeking referral to the Merck Patient Assistance Program for eligibility determination (provided through the Merck Patient Assistance Program, Inc.), the administering physician (or physician at the administering facility) must **REVIEW AND COMPLETE SECTION 7 (ALONG WITH SECTIONS 1 THROUGH 5)**

COMPLETE THE APPROPRIATE SECTIONS OF THE ENROLLMENT FORM ACCORDING TO THE INSTRUCTIONS ABOVE AND FAX TO 800-977-1957.

1 PATIENT INFORMATION (REQUIRED)

Patient Name: _____

DOB (MM/DD/YYYY): _____ Gender: ○ M ○ F

Resides in US / US Territories: ○ Yes ○ No

Street Address (no PO Box): _____

City/State/Zip: _____

Phone (Home): _____ (Other): _____

Email: _____

REQUIRED FOR THE MERCK PATIENT ASSISTANCE PROGRAM AND THE MERCK CO-PAY ASSISTANCE PROGRAM

Current annual gross household income: $_____

(Please include: before-tax wages, pension, interest/dividends, Social Security benefits, and any other sources of income.)

Number of household members (including patient): _____

Patient Name: _____

2 INSURANCE INFORMATION (REQUIRED)

PLEASE INCLUDE A FRONT AND BACK COPY OF INSURANCE CARD(S)

Primary Insurance: _____ ○ Patient has no insurance

(including Medicaid, Medicare, veterans' benefits, private insurers)

Plan name and state: _____

Phone (customer service): _____ Name of Policy holder: _____

Policy holder DOB (mm/dd/yyyy): _____ Policy holder relationship to patient: _____

Policy ID #: _____ Group #: _____

Secondary / Supplemental Insurance: _____

(including Medicaid, Medicare, veterans' benefits, private insurers)

Plan name and state: _____

Phone (customer service): _____ Name of Policy holder: _____

Policy holder DOB (mm/dd/yyyy): _____ Policy holder relationship to patient: _____

Policy ID #: _____ Group #: _____

3 DIAGNOSIS / TREATMENT INFORMATION (REQUIRED)

Please indicate the diagnosis code(s): ○ A04.71 ○ A04.72 ○ Other _____

Anticipated administration date: _____

Patient history: ○ Initial episode ○ Prior episode in the past six months

4 PHYSICIAN INFORMATION (REQUIRED)

Physician name: _____

Physician address: _____

City/State/Zip: _____

Physician tax ID #: _____ Physician NPI #: _____ Physician license #: _____

Facility name: _____

Facility tax ID #: _____ Facility NPI #: _____

Facility contact person: _____

Facility phone: _____ Facility fax: _____

Email: _____

Continues on next page

Patient Name: _____

4 PHYSICIAN INFORMATION (CONTINUED)

Administration Location:

Practice/Facility Name: _____

Phone: _____ Fax: _____

Address: _____

City/State/Zip: _____

Facility tax ID #: _____ Facility NPI #: _____

5 PHYSICIAN OR AUTHORIZED REPRESENTATIVE SIGNATURE AND DECLARATION (REQUIRED)

By signing this certification, you are requesting The Merck Access Program assist your patient with initiating a benefits investigation and/or obtaining information about the prior authorization or appeals process.

MUST CONTAIN ORIGINAL SIGNATURE

By signing below, I represent and warrant the following:

- This request has been prepared exclusively by the physician, physician office or authorized facility representative identified in this request ("my Facility").
- My Facility has obtained written authorization from the patient identified in this request to disclose the patient's personal health information (PHI), including information relating to the patient's medical condition and prescription medications and the information disclosed in this patient enrollment form, to The Merck Access Program, sponsored by Merck Sharp & Dohme Corp. ("Merck"), a subsidiary of Merck & Co., Inc., or the Merck Patient Assistance Program ("Merck PAP"), sponsored by the Merck Patient Assistance Program, Inc. (individually, "a Program"; collectively, "the Programs"), the administrators of the Programs, including their contractors or other affiliates, and for the Programs to use and disclose the information for the purposes of benefits investigation and reimbursement support.
- My Facility has provided the patient identified in this request with the notices necessary to comply with all federal and state laws and regulations relating to medical and/or health privacy, including, but not limited to, the HIPAA Privacy Rule, codified at 45 C.F.R. Parts 160 and 164, as amended from time to time.
- I certify that I, or a physician in my Facility, have determined that the prescribed product is medically appropriate for the patient identified above and that I, or a physician in my Facility, will be supervising the patient's treatment.
- If the patient receives product through the Merck PAP, reimbursement for such product administered to the patient will not be sought from any source.
- I also understand that neither I nor my Facility will receive any reimbursement from Merck, whether for administration fees or otherwise.
- I understand that the Merck PAP reserves the right to conduct periodic audits of my Facility's records, including the physician who will be supervising the patient's treatment, to verify the information provided herein, excluding patient-identifiable data (unless the auditor enters into an appropriate agreement with my Facility to protect an individual's medical privacy).
- I understand that information concerning program participants may be summarized for statistical or other purposes and provided to Merck and/or the Programs.
- I verify that the information provided is complete and accurate to the best of my knowledge.
- My patient is not available or able to sign this enrollment form. I represent and warrant that I explained The Merck Access Program to my patient, that he or she has consented to be enrolled in The Merck Access Program, and that The Merck Access Program may contact my patient, his or her personal representative, or other health care professionals to share information and/or obtain additional information that may assist my patient in obtaining his or her medication.

Authorized facility representative original signature: _____

Date: _____

Authorized facility representative name (please print): _____

To report an adverse event to a specific Merck product, including death due to any cause, please contact the Merck National Service Center at 1-800-444-2080.

Patient Name: _____

6 THE MERCK CO-PAY ASSISTANCE PROGRAM TERMS AND CONDITIONS

The Co-pay Assistance Program is not insurance.

Terms and Conditions for the Co-pay Assistance Program for ZINPLAVA™ (bezlotoxumab) Injection 25mg/mL:

- To receive benefits under the Co-pay Assistance Program for ZINPLAVA™ (bezlotoxumab) Injection 25mg/mL ("Program Product") the patient must enroll in the Co-pay Assistance Program and be accepted as eligible.
- Patient must be prescribed the Program Product for an FDA-approved indication.
- Patient must be 18 years of age or older and must have private health insurance that provides coverage for the cost of the Program Product under a medical benefit plan. Patient must have a maximum Annual Gross Household Income of less than or equal to 700% of the current Federal Poverty Level.
- **The Co-pay Assistance Program is not valid for patients covered under Medicaid (including Medicaid patients enrolled in a qualified health plan purchased through a health insurance exchange [marketplace] established by a state government or the federal government), Medicare, a Medicare Part D or Medicare Advantage plan (regardless of whether a specific prescription is covered), TRICARE, CHAMPUS, Puerto Rico Government Health Insurance Plan ("Healthcare Reform"), or any other state or federal medical or pharmaceutical benefit program or pharmaceutical assistance program (collectively, "Government Programs"). The Co-pay Assistance Program is not valid for uninsured patients.**
- Patient must have an out-of-pocket cost for the Program Product and be administered the Program Product prior to the expiration date of the Co-pay Assistance Program. The benefit available under the Co-pay Assistance Program is valid for the patient's out-of-pocket cost for the Program Product only. It is not valid for any other out-of-pocket costs (for example, office visits charges or medication administration charges) even if such costs are associated with the administration of the Program Product. Claim for Program Product must be submitted by physician to patient's private health insurance separately from other services and products.
- **Patient must pay the first $100 of co-pay on the administration of Program Product.** The benefit available under the Co-pay Assistance Program is limited to the amount the patient's private health insurance company indicates on the Explanation of Benefits (EOB) that the patient is obligated to pay for the Program Product, less $100, up to a maximum benefit of $3,700 for one (1) vial of Program Product. If two (2) vials of Program Product are required to be administered in one infusion, the patient is obligated to pay for the Program Product, less $100, up to a maximum benefit of $7,500. Co-pay assistance is available on a subsequent administration of Program Product, provided patient remains enrolled in the Program and remains eligible, provided however, that co-pay assistance is not available on any administration of Program Product that occurs less than 100 days after any previous administration of Program Product for which co-pay assistance was sought. Subsequent administration is subject to all Terms and Conditions.
- An EOB from patient's private health insurance must be submitted, along with all other required documentation in support of the Co-Pay Assistance Program claim, within **180 days** of the date of the EOB for patient to receive co-pay assistance benefit; provided, however, that no EOB or required documentation may be submitted more than **180 days** after the expiration date of Co-pay Assistance Program. The EOB must reflect the patient's out-of-pocket cost for the Program Product and submission of the claim by the patient's physician for the cost of the Program Product.
- Patient and physician agree not to seek reimbursement for all or any part of the benefit received by the patient through the Co-pay Assistance Program. Patient and physician are responsible for reporting receipt of Co-pay Assistance Program benefits to any insurer, health plan, or other third party who pays for or reimburses any part of the medication cost paid for by the Co-pay Assistance Program, as may be required.
- Patient must be a resident of the United States or the Commonwealth of Puerto Rico. Product must originate and be administered to patient in the United States or the Commonwealth of Puerto Rico.
- The Program may apply to patient out-of-pocket costs incurred for Program Product within 90 days prior to the date patient is enrolled in the Co-pay Assistance Program.
- All information applicable to the Co-pay Assistance Program requested on this form must be provided, and all certifications must be signed. Forms that are modified or do not contain all the necessary information will not be eligible for benefits under the Co-pay Assistance Program.
- No other purchase is necessary.
- **The Co-pay Assistance Program is not insurance.**
- The Co-pay Assistance Program form may not be sold, purchased, traded, or counterfeited. Void if reproduced.
- The Co-pay Assistance Program is void where prohibited by law, taxed, or restricted. The Co-pay Assistance Program is not transferable. No substitutions are permitted.
- The Co-pay Assistance Program benefit cannot be combined with any other Co-pay Assistance Program, free trial, discount, prescription savings card, or other offer. Benefits are not available through this Co-pay Assistance Program for product purchased by patient at a pharmacy, even if later administered in a physician office or outpatient institution.
- Merck reserves the right to rescind, revoke, or amend the Co-pay Assistance Program at any time without notice.
- Data related to patient's receipt of Co-pay Assistance Program benefits may be collected, analyzed, and shared with Merck, for market research and other purposes related to assessing Co-pay Assistance Programs. Data shared with Merck will be aggregated and de-identified, meaning it will be combined with data related to other Co-pay Assistance Program redemptions and will not identify patient.
- **Expiration Date: 12/31/2019.**

Patient Name: _____

PATIENT CERTIFICATION

To be completed by patient or legal representative ONLY

By signing this certification, you are requesting The Merck Access Program to assist you in enrolling in the Merck Co-pay Assistance Program, if eligible.

I certify that I have read and understand the Terms and Conditions of the Co-pay Assistance Program. I certify that I meet the eligibility requirements listed in the Terms and Conditions and that the information I am providing on this form is true and correct.

I certify that I have private insurance and that no part of the costs associated with the Program Product for which I am seeking a benefit under the Co-pay Assistance Program was or will be covered or reimbursed by a Government Program, as that term is defined in the Co-pay Assistance Program Terms and Conditions.

I understand that if I begin to have coverage under any Government Program or if my state prohibits the redemption of manufacturer Co-pay Assistance (coupons) at any time, I will no longer be eligible to receive benefits under the Co-pay Assistance Program. If I am enrolled in a qualified health plan purchased through a health insurance exchange established by a state government or the federal government (QHP), I understand that if the federal government or my state government prohibits the redemption of manufacturer Co-pay Assistance (coupons) by enrollees in QHPs at any time, I will no longer be eligible to receive benefits under the Co-pay Assistance Program.

I certify that my insurance company has not prohibited the redemption of manufacturer Co-pay Assistance (coupons) for the Program Product and I understand that if at any time my insurance company prohibits the redemption of manufacturer Co-pay Assistance (coupons) for the Program Product, I will no longer be eligible to receive benefits under the Co-pay Assistance Program.

I understand that I am responsible for reporting receipt of Co-pay Assistance Program benefits to any insurer, health plan, or other third party who pays for or reimburses any part of the medication cost paid for by the Co-pay Assistance Program, as may be required.

I agree not to seek reimbursement for all or any part of the benefit I receive through the Co-pay Assistance Program. I understand that my physician/physician's office will submit a claim to my private insurance company for the Program Product administered to me.

I understand that any benefit I am eligible for under the Co-pay Assistance Program may be paid directly to my physician/physician's office, on my behalf, or, if I have already paid my share of the cost of the Program Product, may be paid directly to me. I may choose to authorize my physician to submit the Explanation of Benefits received from my private insurance company to the Co-pay Assistance Program and to receive, on my behalf, any benefit for which I am eligible under the Program. I understand that my physician/physician's office will apply any amounts received from the Co-pay Assistance Program toward the satisfaction of my obligation for the cost of the Program Product only. I understand that I am responsible to pay my physician/physician's office the amount I owe per administration of Program Product consistent with the applicable Terms and Conditions of the Co-pay Assistance Program, and any balance owed to my physician/physician's office not covered by the Co-pay Assistance Program. If I have already paid my share of the cost of the Program Product, I will seek the amount of the benefit paid on my behalf from the Co-pay Assistance Program back from my physician/physician's office. Alternatively, if I have already paid my physician for my share of the cost of the Program Product, I may submit to the Co-pay Assistance Program the Explanation of Benefits I (or my physician) received from my private insurance company indicating the amount I am obligated to pay for the cost of the Program Product, along with all required documentation, including an invoice from my physician's office and a receipt reflecting the amount I paid my physician for the cost of the Program Product. I understand that the Co-Pay Assistance Program will deny any claim for Co-Pay Assistance for which inadequate, illegible, or unclear documentation has been received. I understand that any benefit for which I am eligible under the Co-Pay Assistance Program will be paid only one time, either to my physician on my behalf or directly to me.

I understand that I am free to switch physicians at any time without affecting my eligibility to receive benefits under the Co-pay Assistance Program, provided, however, that my new physician must complete the information required on the form, including the physician certification, before any Co-pay Assistance Program benefit for which I am eligible may be paid to such physician/physician's office on my behalf.

I will inform the Co-pay Assistance Program immediately in the event I become ineligible to receive benefits under the Program Terms and Conditions or if my insurance or income changes.

Signature of patient, parent, legal guardian, or legal representative: _____

Date: _____

Name of signing party (please print): _____

Relationship to patient (if other than patient signing): _____

Patient Name: _____

ADMINISTERING PHYSICIAN CERTIFICATION

To be completed by an Administering Physician ONLY – *a signature from an authorized representative will NOT be accepted.*

I, a licensed health care professional, certify that the Program Product has been prescribed to the patient indicated on this form in the exercise of the prescriber's independent medical judgment for an FDA-approved indication.

I have read and agree to the Terms and Conditions of the Co-pay Assistance Program. I certify that, to the best of my knowledge, the patient meets the criteria set forth in the Terms and Conditions, and that the information I am providing on this form is true and correct.

I certify that I/my office will not take into account the fact that the patient may receive a benefit from the Co-pay Assistance Program when determining the amount of any charge(s) to the patient. I certify that I/my office will not charge the patient any fee to complete this form and I/my office will not advertise or otherwise use the Co-pay Assistance Program as means of promoting my services or the Program Product.

I certify that the claim I submit/my office submits to the patient's private health insurer for payment of the Program Product will have the Program Product listed separately from any claim for medication administration or any other items or services provided to the patient.

I understand that I am/my office is responsible for reporting receipt of Co-pay Assistance Program benefits to any insurer, health plan, or other third party who pays for or reimburses any part of the medication cost paid for by the Co-pay Assistance Program, as may be required.

I certify that I/my office will not seek reimbursement for all or any part of the benefit received by the patient through the Co-pay Assistance Program.

I understand that the patient's benefit received under the Co-pay Assistance Program may be paid directly to me/my office by the Co-pay Assistance Program on behalf of my patient, or, if my patient has already paid the patient's share of the cost of the Program Product, may be paid directly to the patient. I/my office will apply any amounts received from the Co-pay Assistance Program to the satisfaction of the patient's obligation for the cost of the Program Product only. If the patient's Co-pay Assistance Program benefit is paid to me/my office on behalf of my patient and I/my office already received payment from the patient for the patient's share of the cost of the Program Product, I/my office will refund the amounts received (minus the patient's obligation per administration in accordance with the Program Terms and Conditions) back to the patient.

I understand and agree that the certifications I am providing in this Physician Certification apply to the patient indicated on this form and to any other patient enrolled in the Co-pay Assistance Program who I treat with the Program Product and any claim I submit/my office submits for Co-pay Assistance Program benefits on the patient's behalf. I understand that I may be asked to sign a new Physician Certification if the Terms and Conditions of the Co-pay Assistance Program for the Program Product change.

Administering physician's original signature: _____

Date: _____

Physician name: _____

Physician address: _____

City/State/Zip: _____

Physician tax ID #: _____ Physician NPI #: _____ Physician license #: _____

Is physician licensed in Vermont? Yes ○ No ○ If yes, provide Vermont license #: _____

Patient Name: _____

7 THE MERCK PATIENT ASSISTANCE PROGRAM (provided through the Merck Patient Assistance Program, Inc.)

By signing this certification, you are requesting The Merck Access Program to refer you to the Merck Patient Assistance Program.

MUST CONTAIN ORIGINAL SIGNATURE

THE MERCK PATIENT ASSISTANCE PROGRAM (provided through the Merck Patient Assistance Program, Inc.; to be completed by patient or legal representative)

APPLICANT DECLARATIONS AND AUTHORIZATIONS

I certify that all of the information provided in this application, including information about household income, is complete and accurate.

I understand that Merck PAP assistance will terminate if the Merck PAP becomes aware of any fraud or if this medication is no longer prescribed for me. I understand that completing this application does not ensure that I will qualify for patient assistance. I certify that I will not seek reimbursement or credit for this prescription from any insurer, health plan, or government program. If I am a member of a Medicare Part D plan, I will not seek to have the prescription or any cost associated with it counted as part of my out-of-pocket cost for prescription drugs.

I understand that Merck PAP reserves the right to modify the application form, modify or discontinue this Program, or terminate assistance at any time and without notice. I authorize Merck PAP and its affiliates to forward the prescription to a dispensing pharmacy on my behalf. Merck PAP is not acting as a dispensing pharmacy. Merck PAP is not responsible for verifying any information contained in the prescription forwarded as part of the enrollment process, including, without limitation, allergies, medical conditions, or other medications being taken by me.

I understand that I will notify the Merck PAP immediately if anything changes with my prescription, income or my insurance coverage.

I understand that the Merck PAP reserves the right to request documentation to verify the information provided in this application for purposes of determining my eligibility for assistance, and to conduct periodic audits of my enrollment, including the physician who will be supervising my treatment, to verify the information provided herein.

I understand that assistance received through the Merck Patient Assistance Program is not insurance.

Signature of patient, parent, legal guardian, or legal representative: _____

Date: _____

Name of signing party (please print): _____

Relationship to patient (if other than patient signing): _____