

The Merck Access Program 2019 ENROLLMENT FORM

KEYTRUDA®
(pembrolizumab) Injection 100 mg

Phone: 855-257-3932, Fax: 855-755-0518 • The Merck Access Program, PO Box 29067, Phoenix, AZ 85038

TO GET STARTED, COMPLETE THE ENROLLMENT FORM AND FAX IT TO 855-755-0518. IF REQUESTING A REFERRAL TO THE MERCK PATIENT ASSISTANCE PROGRAM, PLEASE INCLUDE A PRESCRIPTION FOR KEYTRUDA.

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

- ☐ Patient Benefit Investigation and/or information about the Prior Authorization or Appeals Process
- ☐ Merck Co-pay Assistance Program
- ☐ Referral to the Merck Patient Assistance Program for eligibility determination (provided through the Merck Patient Assistance Program, Inc.)

PATIENT INFORMATION

Patient is a US resident Yes ☐ No ☐

Patient name: _____ Date of birth: _____ Sex: M ☐ F ☐

Address: _____ City/state/zip: _____
(Street address only, no PO boxes)

Phone (home): _____ (work): _____ (other): _____

E-mail: _____

INSURANCE INFORMATION

PLEASE COMPLETE ALL THAT APPLY AND **INCLUDE A FRONT AND BACK COPY OF INSURANCE CARD** FOR EACH TYPE OF INSURANCE

☐ Patient Has No Insurance Patient Has Insurance Through Medicare: ☐ Part A ☐ Part B ☐ Part D ☐ Medicare Advantage

Primary insurer (including Medicaid, Medicare, veterans benefits, and private insurers)

Plan name and state: _____

Phone number for customer service: _____ Name of policyholder: _____

Policyholder date of birth: _____ Policyholder relation to patient: _____

Group no.: _____ Policy ID no.: _____

Secondary/supplemental insurer

Plan name and state: _____

Phone number for customer service: _____ Name of policyholder: _____

Policyholder date of birth: _____ Policyholder relation to patient: _____

Group no.: _____ Policy ID no.: _____

REQUIRED FOR THE MERCK PATIENT ASSISTANCE PROGRAM

Current annual gross household income (parent/guardian if patient is under age 18): \$ _____

Number of household members (including patient): _____

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

PATIENT AUTHORIZATION

I understand that, before I may have communications with The Merck Access Program, sponsored by Merck Sharp & Dohme Corp. ("Merck"), a subsidiary of Merck & Co., Inc., or receive assistance from 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 representatives, will need to obtain, review, use, and disclose my personal health information ("PHI"), including information relating to my medical condition and prescription medications and the information included in this patient enrollment form.

I therefore authorize each of my physicians, pharmacies, and health plans to disclose my PHI, as necessary, to (i) the administrators of the Programs and their contractors or representatives, in order to verify my eligibility to enroll in the Programs and to enroll me in the Programs for which I am eligible; and (ii) Covance Market Access ("Covance") and its administrators, contractors, representatives, or third-party service partners to provide reimbursement support and to investigate insurance coverage in connection with The Merck Access Program.

I also authorize the administrators of the Programs and Covance, and their respective contractors or representatives to (i) use my PHI to provide the services described in this enrollment form, including to communicate with me by U.S. postal mail, telephone, text, or e-mail and to prepare summaries that do not include my PHI for statistical purposes; and (ii) share my PHI with one another and with my physicians and pharmacists as well as with Medicare, my health plans, and their administrators, contractors, or representatives, in order for them to coordinate my benefits, provide, when applicable, reimbursement support, and investigate my insurance coverage.

I also authorize the administrators of the Programs and Covance and their contractors, representatives, and third-party services partners to disclose my PHI to authorized representatives of Merck as necessary to ensure compliance with the rules of the Programs. I also authorize Merck's authorized representatives to use my PHI to communicate with the administrators of the Programs, Covance, their contractors, representatives or third-party services partners, my physicians, pharmacies, and me for compliance purposes.

If I have designated a Personal Representative, I authorize the Programs, their administrators, and their third-party service partners to use my PHI to contact the person I have designated as my Personal Representative for the purpose of verifying the information I have provided in this form and/or coordinating the provision of benefits that may be available to me under the Programs and to disclose my PHI, including information provided in this enrollment form, to my Personal Representative for the purposes described in this paragraph.

I understand that the PHI disclosed pursuant to this authorization, once disclosed, may not be governed by federal privacy law and may be subject to re-disclosure, but I also understand that the administrators of the Programs and their contractors and other representatives intend to use and disclose my PHI only for the purposes described in this authorization. I further understand that if I choose not to provide this authorization, it will not affect my eligibility for, or receipt of, treatment, including Merck products, or health care insurance benefits, but that I will not be able to receive any assistance from the Programs for which I may be eligible.

I understand that I may cancel this authorization at any time by telephoning The Merck Access Program at (855) 257-3932 or by mailing a written request for cancellation to The Merck Access Program, PO Box 29067, Phoenix, AZ 85038. I understand that canceling my authorization will mean that my physicians, pharmacies, and health plans, as well as Covance and the Programs, their respective administrators, and their contractors and representatives, may no longer rely on the authorization to use or disclose my PHI, but that any use or disclosure of such information that occurs before my cancellation is received will be unaffected by my cancellation.

Patient name: _____

PATIENT AUTHORIZATION *(continued)*

I understand that if I do not cancel this authorization, the authorization will expire 15 months from the date of signature (or the maximum period allowed by applicable state law, if less than 15 months). The administrators of the Programs will retain the information I have submitted in accordance with Merck's records retention policy.

I understand that I am entitled to receive a copy of this authorization once it has been signed.

By signing, I certify that I have read and agree to the above Patient Authorization based on the support I have requested.

**PATIENT
SIGNATURE**

Signature of patient, parent,

legal guardian, or legal representative: _____ Date: _____

Name of signing party (please print): _____

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

THE MERCK CO-PAY ASSISTANCE PROGRAM TERMS AND CONDITIONS

To receive benefits under the Co-pay Assistance Program, the patient must enroll in the Co-pay Assistance Program and be accepted as eligible. Patient may contact The Merck Access Program for current Program Product(s) subject to these Terms and Conditions.

- Patient must be prescribed the Program Product for an FDA-approved indication.
- Patient must have private health insurance that provides coverage for the cost of the Program Product under a medical benefit plan.
- **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 visit 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 provider to patient's private health insurance separately from other services and products.
- **Patient must pay the first \$25 of co-pay per 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 \$25, up to an annual maximum. The maximum Co-pay Assistance Program benefit per patient, per calendar year (January 1 through December 31), is \$25,000.
- An EOB from patient's private health insurance must be submitted within **180 days** of the date of the EOB for patient to receive co-pay assistance benefit; provided, however, that no EOB 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 provider for the cost of the Program Product.
- Patient and provider 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 provider 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, subject to annual Program maximum and the applicable Terms and Conditions based on Program Product administration date. Patient or provider may contact The Merck Access Program for more information.
- 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.
- If acquiring Program Product from a Specialty Pharmacy (to be later administered in a physician office or outpatient institution), additional documentation may be required.
- 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.
- These Terms and Conditions are valid for Program Product administered between January 1, 2019, and December 31, 2019.
- **Expiration Date: 12/31/2019.**

Patient name: _____

PATIENT CERTIFICATION: THE MERCK CO-PAY ASSISTANCE PROGRAM

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 provider will submit a claim to my private insurance company for the Program Product administered to me. I authorize my provider to submit the

Explanation of Benefits received from my private insurance company to the Co-pay Assistance Program and to receive, on my behalf, if applicable, any benefit for which I am eligible under the Program. I understand that my provider 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 provider 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 provider not covered by the Co-pay Assistance Program. I understand that co-pay assistance for any administration of Program Product to me between January 1, 2018 and December 31, 2018 is subject to the 2018 Co-pay Assistance Program Terms and Conditions.

I understand that any benefit I am eligible for under the Co-pay Assistance Program will be paid directly to my provider, on my behalf, if applicable, or directly to me. If I have already paid my provider for my share of the cost of the Program Product for which I later receive a benefit through the Co-pay Assistance Program, I will seek the amount, less the amount I owe per administration, if applicable in accordance with the Co-pay Assistance Program Terms and Conditions, back from my provider.

If acquiring Program Product from a Specialty Pharmacy (to be later administered in a physician office or outpatient institution), I understand that additional documentation may be required.

I understand that I am free to switch providers at any time without affecting my eligibility to receive benefits under the Co-pay Assistance Program, provided, however, that my new provider must complete the information required on the form, including the Health Care Provider and/or Specialty Pharmacist Certifications, as applicable, before any Co-pay Assistance Program benefit for which I am eligible may be paid, if applicable, to such provider 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 changes.

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

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.

PATIENT ACKNOWLEDGMENT AND SIGNATURE

If another person will be legally signing on behalf of the patient or if the patient would like to designate a person to act on his or her behalf to verify information and coordinate provisions of the programs described in this enrollment form, PLEASE INCLUDE A COMPLETED REPRESENTATIVE'S FORM WITH THIS ENROLLMENT FORM.

By signing, I certify that I have read and agree to the above Patient Certification and the terms and conditions of the Merck Co-Pay Assistance Program and the Merck Patient Assistance Program, as applicable, based on the support I have requested. By signing, I also certify that all information that I have provided in this application is complete and accurate.

PATIENT
SIGNATURE

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

Name of signing party (please print): _____

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

☐ I would like to learn more about "KEY+YOU" the free Patient Support Program for people taking KEYTRUDA. If I am eligible and decide to enroll, I can receive information and resources to support me in connection with my treatment with KEYTRUDA.

I understand that my personal information is needed for this program referral. I agree to allow my information collected as part of The Merck Access Program to be shared with the agents of the KEY+YOU Patient Support Program and to allow those agents to contact me, leave a voice mail, or leave a message with someone else who answers this number, to discuss the KEY+YOU Program and its support. I understand that the use and disclosure of my personal information in connection with referral to the KEY+YOU Program will be limited to the KEY+YOU Program and its agents. I also understand that my request for referral to the KEY+YOU Program does not in any way affect my enrollment into The Merck Access Program and does not obligate me to participate in the KEY+YOU Program.

Patient name:_____

MERCK PAP—PATIENT ATTESTATION OF FINANCIAL HARDSHIP

The Merck PAP is designed primarily for individuals who do not have prescription drug or health insurance coverage; however, individuals with insurance coverage may still request assistance if they experience a financial hardship (i.e., the individual cannot afford the deductible, co-pay, co-insurance, or other cost sharing requirement of his or her insurance plan). If you would like to be considered for an exception to the Merck PAP's insurance criteria, please carefully review the attestations below and sign and date this section.*

*The Merck PAP evaluates all requests for an exception to its insurance criteria based on a financial hardship on a case-by-case basis, and cannot guarantee that an exception will be made.

1. I attest that the information provided in this enrollment form is complete and accurate. If my Benefit Investigation determines that my insurance does not fully cover my prescription cost, I would like to be considered for a financial hardship exception to the Merck PAP's insurance criteria. I understand that the determination of whether to approve a financial hardship exception resides exclusively with the Merck PAP.
2. I understand that if I have Medicare coverage, my eligibility will automatically expire on December 31 of the current calendar year and it will be necessary for me to submit a new application before December 31 for program determination of eligibility for the following year. If I fail to re-enroll before December 31, I understand that I will no longer receive my medication from the Merck Patient Assistance Program.

I have Medicare Part B coverage (please check applicable box)

Yes ☐ No ☐

3. I understand that if I have private prescription drug coverage, my eligibility will automatically expire 1 year from my date of enrollment and I must re-enroll for program determination of eligibility for the following year.
4. I attest that I will notify the Merck Patient Assistance Program immediately if anything changes with my prescription or my insurance coverage.
5. I understand that the Merck Patient Assistance Program reserves the right to request additional documentation from me to support my request for an exception based on my financial hardship including, for example, documents relating to my income.

I understand it is my responsibility to promptly inform the Program of any information that changes from what is being submitted on this form.

PATIENT
SIGNATURE

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: _____

HEALTH CARE PROVIDER INFORMATION (to be completed by health care provider)

Health care provider name: _____

Practice/Facility name: _____

Health care provider tax ID no.: _____

Practice tax ID no.: _____

Health care provider NPI no.: _____

Practice NPI no.: _____

Health care provider State license no.: _____

Practice/Facility address: _____

Health care provider State license no. expiration date: _____

(Street address only, no PO boxes)

Address: _____

(Street address only, no PO boxes)

City/state/zip: _____

City/state/zip: _____

Phone: _____ Fax: _____

Office contact person: _____

Office contact number: _____

E-mail: _____

Please list primary diagnosis code:**Please list primary tumor type:****Next treatment date:****HEALTH CARE PROVIDER ATTESTATION**

By signing below, I represent and warrant the following:

- This Enrollment Form has been prepared exclusively by the health care provider or health care provider office identified in this Enrollment Form.
- By signing below, I represent and warrant that I am authorized pursuant to the laws of my state of license to prescribe KEYTRUDA.
- I or others in my health care provider practice group ("my Practice") have obtained written authorization from the patient named in this Enrollment Form that complies with the requirements of the HIPAA Privacy Rule, 45 C.F.R. § 164.508, and authorizes me and the Practice, as well as the patient's health insurance plan(s), 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 Enrollment Form to The Merck Access Program (the "Access Program"), and the Merck Patient Assistance Program ("Merck PAP") (collectively, "the Programs") and Covance Market Access, and authorizes the Programs and Covance Market Access (together with their respective administrators, contractors or other affiliates) to use and disclose the PHI for purposes of benefits investigation and reimbursement support.

- I certify that I, or a health care provider in my Practice, have determined that the prescribed product is medically appropriate for the patient identified above and that I, or a health care provider in my Practice, will be supervising the patient's treatment.
- If the patient receives product through the Merck PAP, neither I nor my Practice will seek reimbursement for such product administered to the patient from any source.
- Neither I nor my Practice will receive any reimbursement from Merck, whether for administration fees or otherwise.
- I understand that information concerning Program participants may be summarized for statistical or other purposes and provided to Merck and/or the Programs only for use in an aggregated, de-identified format.
- I and my Practice grant Programs the right to conduct periodic audits of my Practice's records to verify the information provided herein, excluding patient-identifiable data (unless the auditor enters into an appropriate agreement with my Practice to protect an individual's medical privacy).
- I consent to receive communications related to the Program by telephone, e-mail, and/or fax.
- The information provided is complete and accurate to the best of my knowledge.

HEALTH CARE PROVIDER CERTIFICATION: THE MERCK CO-PAY ASSISTANCE PROGRAM

I, a licensed health care professional, certify that I have prescribed the Program Product to the patient indicated on this form in the exercise of my 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 will be paid directly to me/my office by the Co-pay Assistance Program on behalf of my 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 I/my office already received payment from the patient for the patient's share of the cost of the Program Product for which the patient receives a benefit through the Co-pay Assistance Program, 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 Health care provider 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 Health care provider Certification if the Terms and Conditions of the Co-pay Assistance Program for the Program Product change.

By signing, I certify that I have read and agree to the above Attestation. I also have read and agree to the above Certification (if applicable based on the support my patient requested).

**HEALTH CARE
PROVIDER
SIGNATURE****Health care provider signature:** _____ **Date:** _____**Health care provider name (please print):** _____**Health care provider designation (MD, DO, NP, PA, Other):** _____**Is health care provider licensed in Vermont?** Yes ☐ No ☐ **If yes, provide Vermont license no.:** _____**To report an adverse event to a specific Merck product, including death due to any cause, please contact the Merck National Service Center at 800-444-2080.**