Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg

Mirena® (levonorgestrel-releasing intrauterine system) 52 mg

Skyla® (levonorgestrel-releasing intrauterine system) 13.5 mg

BAYER

ARCH - Bayer US Patient Assistance Foundation Application Form – Page 1 of 2
Please return completed application and all required documentation to ARCH, PO Box 5670, Louisville, KY 40255 or Fax to 1-877-229-1421. For inquiries, call 1-877-393-9071.

A. PROVIDER INFORMATION (Sections A, B and C must be completed by the Provider)

Provider Name: _____

Facility Name: _____

Address: _____

City: _____ State: _____ ZIP Code: _____

Phone: _____ Fax: _____

Contact Person: _____ NPI#: _____

Email Address: _____

Please indicate shipping address if different from above:

Facility Name: _____

Address: _____

City: _____ State: _____ ZIP Code: _____

Please indicate if your clinical setting is (check all that apply):

☐ Title X ☐ Public Health Clinic (State, City, County)

☐ Private ☐ Hospital ☐ Other _____

B. Prescription Information

Date: _____ Patient Name: _____ DOB: _____

Product selection (choose one): ☐ Kyleena® ☐ Mirena® ☐ Skyla® **Quantity: 1 unit Take: As directed Refills: 0**

☐ Please check here for a replacement unit Date of Service: _____

Note: Proof of insertion required for replacement unit. See application and eligibility criteria on page 3.

C. Provider Declaration and Authorization

I verify that, to the best of my knowledge, the information provided in this application is complete and accurate, and that this patient does not have Medicaid or any other form of insurance or other means to obtain Kyleena, Mirena or Skyla. I understand that the patient must qualify financially and meet the program criteria to be eligible for assistance. I also understand that Bayer reserves the right at any time, and without notice, to modify the application form; to modify or discontinue this program and its eligibility criteria; or to terminate assistance. I also understand that the product I receive is not a sample and that Kyleena, Mirena or Skyla will not be billed to any third-party payer; resold or offered for sale, trade, or barter; and will not be returned for credit. My signature below confirms that Kyleena, Mirena or Skyla will be provided free of charge to this patient as deemed medically appropriate.

_____ _____ _____

Provider Signature **Date** Print Name

D. PATIENT INFORMATION (Sections D, E, F, and G [signature on page 2] must be completed by the Patient)

Patient Name: _____

Address: _____ City: _____ State: _____ ZIP Code: _____

Phone: _____

Drug allergies (if any): _____

E. Coverage and Insurance

Do you have Medicaid?

☐ Yes ☐ No

Do you have any other form of private or public insurance coverage? ☐ Yes ☐ No

If Yes, please explain why you cannot obtain Kyleena, Mirena or Skyla through that insurance and any steps you have taken to obtain coverage: _____

F. Financial Information/Proof of Income Certification

Please provide proof of income to support declared income below. Failure to include proof of income may delay approval process.

Current annual household income: $ _____

Number of household members dependent on income stated above (include yourself) _____

☐ **Please go to page 2 for patient to review and sign**

☐ **Don't forget to include proof of income documentation**

ARCH - Bayer US Patient Assistance Foundation Application Form – Page 1 of 2
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G. APPLICANT DECLARATION AND AUTHORIZATION

I verify that the information provided in this application and at a later date is complete and accurate. I verify that I do not have any means to obtain Kyleena®, Mirena® or Skyla® ("ARCH Products") through any form of insurance or health coverage. I understand assistance through the Bayer US Patient Assistance Foundation (BUSPAF) depends upon my ability to meet the eligibility criteria for the ARCH program. I also understand that BUSPAF reserves the right at any time without prior notice, to modify the application form; to modify or discontinue this program and its eligibility criteria; or to terminate ARCH assistance. If I experience an adverse event or product technical complaint, I understand that it will be shared with Bayer Pharmacovigilance, and that Bayer may contact my healthcare provider or myself to learn more about the event.

For the limited purposes listed below, I authorize my healthcare providers (including physicians, nurses and pharmacies) and my health insurer(s) to share or disclose my protected health information ("PHI"), including without limitation my name, address, telephone number, medical records, health insurance and financial information to BUSPAF and its contracted agents. These agents include a company that is an administrative contractor that administers the Program dispenses ARCH products and analyzes and produces reports of aggregated, de-identified data. I understand that certain healthcare providers may receive payment or other forms of remuneration from BUSPAF in connection with the use and disclosure of my PHI as described in this authorization.

I authorize the use and disclosure of my PHI for the following purposes: (1) to verify my financial or insurance information; (2) to ensure the accuracy and completeness of this application form; (3) to help with my reimbursement questions; (4) to see if I qualify for patient assistance or copayment assistance, or to refer me to or determine my eligibility for, other programs, foundations, or alternate sources of funding or coverage to help me with the costs of obtaining ARCH Products; (6) to send me educational materials about ARCH Products or other ARCH information that may be of interest to me; (7) for commercial purposes, including to understand how ARCH Products are used across healthcare providers and other market research; (8) to manage supply and availability of ARCH Products; and (9) to comply with applicable law.

I understand that any personal information shown on this application will not be used for any purpose other than those described above unless:

- I give written consent, or
- it is required or permitted under the law, or
- my name and all other identifying information is removed.

I am providing 'written instructions' under the Fair Credit Reporting Act to the Bayer US Patient Assistance Foundation, including its agents, administrators, and service providers, authorizing the Bayer US Patient Assistance Foundation to obtain information from my credit profile and/or other information from Experian Health. I authorize the Bayer US Patient Assistance Foundation, including its agents, administrators, and service providers, to obtain such information solely to determine my eligibility for the Bayer US Patient Assistance Foundation and its Products.

I have read this authorization and or had its contents read to me. I have had an opportunity to ask questions about the uses and disclosures of PHI described above and all of my questions have been answered to my satisfaction. I am signing this authorization voluntarily and I understand that my healthcare providers and health insurer cannot condition my medical treatment or its payment, insurance enrollment, or eligibility for insurance benefits on my signing this form. However, if the information requested about me is not provided, BUSPAF will be unable to determine my eligibility to participate in the ARCH Program and I will not be able to receive assistance obtaining ARCH Products through BUSPAF. I understand that I am entitled to receive a signed copy of this authorization.

This authorization expires at the end of my participation in ARCH Program or earlier if required by state law; however, I can revoke (i.e., take back) this authorization at any time by mailing a written request to Bayer US Patient Assistance Foundation, PO Box 5670, Louisville, KY, 40255, or by faxing a request to 1-877-229-1421, or by calling 1-877-393-9071. I understand that if I revoke this authorization, it will not have any effect on any actions my healthcare providers or my health plan may have taken before receiving the revocation, and will not affect Bayer's ability to use and disclose any information it has already received.

Patient or Patient Representative's Signature **Date** Print Name

If signed by the Patient's representative, please provide a description of the representative's relationship to the Patient and such person's authority to act for the Patient.

March 2018. PP-120-US-0263.

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ARCH - Bayer US Patient Assistance Foundation Application Instructions

Eligibility Requirements

The patient must meet all of the following ARCH program eligibility requirements:

- ✔ Patient does not have access to private or public insurance coverage for Kyleena®, Mirena® or Skyla®
- ✔ Patient meets the ARCH program's financial criteria for assistance, and provides acceptable documentation to support proof of reported income
- ✔ Patient resides in the United States or Puerto Rico, and is under outpatient treatment by a qualified, U.S.-licensed healthcare provider
- ✔ Both patient and provider complete and sign the ARCH Application Form; forms can be submitted by fax or by mail

Please note, income eligibility is based on a percentage of the Federal Poverty Limit and household size. The specific eligibility criteria are not publicly disclosed and are subject to change without notice. All applications are reviewed on a case by case basis.

Product Replacement

Product replacement may be available through ARCH for uninsured patients or patients who do not have coverage for Kyleena®, Mirena® or Skyla®, provided the patient meets certain financial, medical, and insurance criteria.

To request a replacement, please ensure the following are submitted with this completed form:

- ✔ Record of insertion with date of service
- ✔ For patients who have insurance, but whose insurer does not cover the product, a copy of the initial claim denial. An appeal denial may be necessary. A program representative can help explain this requirement
- ✔ Replacement requests must be submitted within 12 months of date of the service

Proof of Annual Household Income Requirements

In addition to the Application Form, proof of annual household income is requested. This can be provided by sending an acceptable form of documentation to the ARCH program.

Acceptable forms of documentation include (please provide one of the following):

- ✔ Federal tax return for the prior tax year; or
- ✔ Statement from the IRS stating that patient does not file a tax return; or
- ✔ Household pay stubs representing 4 consecutive weeks of wages paid within the last 6 months; or
- ✔ A letter of means of support (i.e. food stamps, housing assistance, or any other assistance received); or
- ✔ A statement signed by the patient, stating that the patient has no source of income.

If you have questions about any of the above requirements, please contact one of the ARCH program case coordinators at 1-877-393-9071.

Application Process

Once the completed and signed Application Form has been submitted, including proof of income (either documentation or certification, as described above), the ARCH program case coordinators will review the application and then notify both provider and patient of the outcome.

If the Application is approved, a unit will be shipped directly to the facility shipping address provided on the Application Form. If the Application is incomplete, the ARCH program coordinators will attempt to contact the patient and provider to request the missing information. If the Application is denied, a reason will be provided. The patient may reapply if relevant circumstances change.

Please allow up to 5 business days to receive a response, from the time the complete application is submitted. If you have not heard back within this time frame, please contact the ARCH program at 1-877-393-9071.

March 2018. PP-120-US-0263.