Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg

Mirena® (levonorgestrel-releasing intrauterine system) 52 mg

Skyla® (levonorgestrel-releasing intrauterine system) 13.5 mg

ARCH Patient Assistance Program Application Form – Page 1 of 2
Please return completed application and all required documentation to ARCH, PO Box 29061, Phoenix, AZ 85038 or Fax to 1-877-229-1421

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**

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

The patient must provide proof of income OR the healthcare provider must certify the proof of patient's income.

☐ Documentation enclosed with application to support reported income

Current annual household income: $ _____

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

☐ Certification of health care provider or administrator

Instead of including proof of income documentation, certification from a healthcare provider or administrator may be provided below.

I certify that I have reviewed documentation from the patient to support this patient's annual household income reported above.

Provider Signature: _____

Print Name: _____

Title: _____

Phone: _____

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

☐ **Don't forget to include proof of income documentation (not required if healthcare provider or administrator completes proof of income certification section above)**

ARCH Patient Assistance Program Application Form – Page 2 of 2
Please return completed application and all required documentation to ARCH, PO Box 29061, Phoenix, AZ 85038 or Fax to 1-877-229-1421

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® under Medicaid or any other form of insurance or health coverage. I understand assistance depends upon my ability to meet the eligibility criteria for the ARCH program. 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 authorize the use and/or disclosure of my private health information, described below, which may include "Protected Health Information" or "PHI" as defined by the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"). In general terms, I understand that Protected Health Information is health information that identifies me or that could reasonably be used to identify me. I understand that this authorization is voluntary.

I authorize healthcare providers that treat me or provide health care services to me, including my physicians and pharmacies, and my health insurer(s) to share or disclose my name, address, and telephone number, along with certain medical records and insurance and financial information with respect to my treatment, my eligibility for insurance or patient assistance, the coordination of my treatment, including scheduling, ordering, and the receipt of Kyleena, Mirena or Skyla, and my participation in the ARCH Program (the "Program") to Bayer and its agents as deemed necessary to ensure the accuracy and completeness of this application. These agents include a company that is an administrative contractor that administers the Program, the supplier which dispenses Kyleena, Mirena or Skyla, and a data analytics company which analyzes and produces reports of aggregated data (collectively "Bayer"). I understand that certain healthcare providers may receive payment or other forms of remuneration from Bayer in connection with the use and disclosure of my PHI as described in this authorization. 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.

I allow 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 the Program enrollment 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 Kyleena, Mirena or Skyla; (5) to coordinate my Kyleena, Mirena or Skyla appointments; (6) to send me educational materials, or other Program information that may be of interest to me; (7) for commercial purposes, including to understand how Kyleena, Mirena or Skyla is used across healthcare providers and other market research; (8) to manage supply and availability of Kyleena, Mirena or Skyla; 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, and
- my name and all other identifying information is removed.

This authorization expires at the end of my participation in the Program or 3 years (or earlier if required by state law), from the date of my signature, whichever comes first. I can withdraw (ie, take back) this authorization any time, except to the extent my healthcare provider or health plan insurer has taken action in reliance on my authorization. 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. I can withdraw this authorization by mailing a written request to ARCH Program, PO Box 29061, Phoenix, AZ 85038, or by faxing a request to 1-877-229-1421, or by calling 1-877-393-9071.

My healthcare providers and health plan insurer will not 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, Bayer will be unable to determine my eligibility to participate in the Program and I may thus be unable to participate. 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 authorize the use and disclosure of my information as described in this form. I understand that I am entitled to receive a signed copy of this authorization.

_____ _____

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.

CONFIDENTIALITY NOTICE: The materials in this transmission are private and may contain Protected Health Information. If you are not the intended recipient, be advised that any unauthorized use, disclosure, copying, distribution, or taking of any action in reliance on the contents of this information is strictly prohibited. If you have received this transmission in error, please immediately return it to the sender and delete or destroy it without reading it. Approved for Distribution.

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ARCH Patient Assistance Program 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, Puerto Rico, Guam or the US Virgin Islands, and is under outpatient treatment by a qualified, U.S.-licensed healthcare provider
- ✔ Both patient and provider complete and sign the ARCH Application Form (revised 11/2017); 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. Retroactive assistance is not available.

Proof of Annual Household Income Requirements

In addition to the Application Form, proof of annual household income is required. This can be provided either by sending an acceptable form of documentation to the ARCH program, or by presenting an acceptable form of documentation to a health care provider or administrator who will certify that the patient's income as reported on the ARCH Application Form is accurate.

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.

Instead of sending their documentation to the ARCH program, patients may instead request a health care provider or administrator to certify their reported income is accurate, by providing the following information on the Application Form:

- ✔ Signature, name and title of health care provider or health care administrator, [see ARCH Application Form, Financial Information section],certifying that the patient's reported income is accurate, based on that person's review of income documentation as described above.

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.