

# Rubraca Enrollment and Comprehensive Support Form

Please fill out the sections of this form that apply to you to the best of your ability. Your healthcare provider will complete the rest. A completed form can help identify if circumstances have changed and may prevent coverage delays.

Fax completed form to 1-844-779-7717. Questions? Call 1-844-779-7707.

New Application

Renewal Application

## COMPREHENSIVE SUPPORT PROGRAMS (select all that apply below)\*

QuickStart Program (See section F)

Rubraca Co-pay Assistance Program

Practice Experience Manager  
personalized support

Coverage Link Program (See section  
H—Change in Commercial Coverage)

Patient Assistance Program  
(See section G)

\*All programs and support are subject to eligibility requirements.

## A PATIENT INFORMATION

Patient name (first and last)

Date of birth (mm/dd/yyyy)

Age

Gender

M

F

Last Four of SSN

Address

City

ZIP

State

Home phone

Cell phone

E-mail

Language assistance required?

No

Yes (please specify language)

Care Partner name (first and last)

Care Partner phone

## B INSURANCE INFORMATION

Fill out and attach a legible copy of patient's pharmacy benefit card, front and back. This is the card the patient presents to the pharmacy to fill medications. It is important that the card be presented and properly copied to prevent possible coverage delays.

Do you have any form of prescription drug coverage?

Yes

No

If yes, please provide information on all plans :

Insurer

Plan Name

Policy Number

Secondary Insurer

Plan Name

Policy Number

BIN Number

Other

VA or TRICARE

Medicaid (State)

Medicare Part D (Payer Name)

Social Security "Extra Help"

Yes

No

Patient states they have no insurance

**C PATIENT PROGRAM CONSENT**

**All patients must read the following and provide a signature to use Rubraca support programs.**

I authorize my healthcare providers, health plans and pharmacies (collectively, "Healthcare Organizations") to use and share my personal health information (PHI) related to my medical condition and Rubraca therapy (my "PHI") with pharma& and their agents, third-party contractors or their service providers authorized to administer its patient support programs (i)for reimbursement assistance, (ii)for referral to and enrollment in patient support and/or financial assistance programs,(iii)for providing me with materials and information about my treatment or other programs related to my drug therapy and enrolling me in such programs as I request, (iv)as required or permitted by law. I authorize AssistRx, pharma& and their agents, third party contractors or their service providers authorized to administer the program to use my name, date of birth, and address to estimate my income in conjunction with the eligibility determination process and/or additional demographic information to access my credit information and information derived from public and other sources to estimate my income in conjunction with the eligibility determination process. I understand that, once disclosed pursuant to this authorization, my PHI may no longer be protected under federal or state law and could be disclosed by AssistRx to others, but I understand that AssistRx will make reasonable efforts to keep it private and to disclose it only for the purpose set forth in this authorization. I understand that my pharmacy may receive payment from pharma& in connection with (i) the disclosure of my health information to AssistRx for purposes allowed under this authorization, including but not limited to market research purposes and (ii) the use of my PHI to communicate with pharma& products or services. I understand that my authorization is voluntary and my healthcare providers, health plans, and pharmacies may not base my treatment, payment for treatment, enrollment or eligibility for benefits, on whether I sign this authorization. However, if I do not sign this authorization, it may affect my ability to enroll in pharma& programs. I understand that this authorization will remain valid for 5 years after the date of my signature or such earlier date as required by applicable law, unless I revoke it earlier by canceling my enrollment, which I may do in writing to PO Box 7613, Overland Park, KS 66207 at any time. I understand that my cancellation will not apply to any use or disclosure of my healthcare information by my healthcare providers, health plans or pharmacies before they receive notice of my cancellation.

Patient signature *(required)*

Date

Verbal consent obtained by

Print patient first and last name

Legal representative first and last name *(if patient is unable to sign)*

*If signed by someone other than the patient, please describe your legal authority/power of attorney to sign on behalf of the patient (eg, guardian, custodian, healthcare power of attorney).*

**Please continue on to complete this Enrollment Form and to learn more about Rubraca Comprehensive Support Programs.**

**D PRESCRIBER INFORMATION**

Prescriber name				E-mail	
Practice/Facility name	340B Facility	Yes	#	No	Unknown
NPI #	DEA#				
Address					
City				ZIP	State
Office / Financial Contact(s)					
Phone	Fax				E-mail
Phone	E-mail				

Use my practice's In-Office Dispensary (IOD) **(DO NOT forward to specialty pharmacy)**

Ship to same address as Facility

Ship to different address

We may prefer specialty pharmacy in Rubraca Network *(specialty pharmacy name)*

No specialty pharmacy preference

**E DIAGNOSIS AND PRESCRIPTION**

**Complete the Rubraca prescription in the space provided below or attach separately.**

Patient name *(first and last)* \_\_\_\_\_ Date of birth *(mm/dd/yyyy)* \_\_\_\_\_

Ovarian Cancer Diagnosis *(provide ICD-10 code)*

Prostate Cancer Diagnosis *(provide ICD-10 code)*

**Drug: Rubraca**      DAW *(dispense as written)*

Dosage	300 mg	250 mg	200 mg	Days supply	30 days	Quantity	Refills
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**QuickStart Program**

Dosage	300 mg	250 mg	200 mg	Days supply	15 days	Quantity	Refills (3 max)
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**Directions for use**

The recommended starting dose and schedule for Rubraca is 600 mg taken orally twice daily. If your patient misses a dose of Rubraca, instruct them to take their next dose at their usual scheduled time. Your patient should not take an extra dose to make up for a missed dose.

**Prescriber Directions for use** *(Be sure to specify patient dosing requirements in this space. Failure to do so will cause a delay in treatment.)*

Prescriber signature  
*(MD/NP/PA)*

Date

I have determined that Rubraca is appropriate for treatment of the patient and that the patient is on label. I authorize the Rubraca Patient Support Program to convey the attached prescription on my behalf to the selected specialty pharmacy or in-office dispensary and to receive information on the status and related matters.

**Please note:** Patients who are prescribed Rubraca off-label, will not qualify for Rubraca support or coverage programs.

## F QUICKSTART PROGRAM

**The QuickStart Program helps patients start Rubraca, if they experience coverage delays, regardless of income or insurance. Eligible patients receive a 15 days' supply of Rubraca for up to 60 days (2 months) while coverage is pending or until alternate funding resources have been identified and approved.**

**The following terms and conditions apply:**

- Patients must meet diagnosis and coverage criteria to be eligible. Eligible patients may receive supply of product for up to 60 days only, in 15-day increments, if a coverage issue persists during that time period. No purchase is necessary. Product may not be used for resale or shared with other patients or billed to any insurance carrier. Patients may contact 1-844-779-7707 to find out if they are eligible for this program. pharma& reserves the right to change the terms and conditions of the program or terminate the program without notice.

QuickStart Delivery

Patient Home

Prescriber Office

## G PATIENT ASSISTANCE PROGRAM (PAP)

**If the patient is uninsured or cannot afford medication and would like to apply for the Patient Assistance Program (PAP), please complete below. The patient application may be subject to audit or request for additional information. If insurance is denied, please provide proof of denial.**

Yearly gross household income \$

Household size

*(Before taxes and expenses)*

*(Patient, Spouse, and Dependents on tax return)*

pharma& policy prohibits prescribers from charging the patient any fee for enrollment or other activities associated with the patient's participation in the Patient Assistance Program. No claim may be made to any third-party payer (eg, Medicaid, Medicare, private insurance, etc) for payment for product provided under Patient Assistance Program (PAP). Patients may not seek reimbursement from their Part D plan or any other insurer for the free product they receive through the PAP.

Product may not be used for resale, returned for credit, or shared with other patients. pharma& reserves the right to rescind, revoke, or change the program at any time without notice.

**Please note:** If the patient does not provide a signature on page 2, consent will be acquired at a later stage for enrollment in the Patient Assistance Program.

Free drugs are provided to Medicare Part D patients outside of the Medicare Part D benefit. Free product received will not count toward the patient's Medicare true-out-of-pocket (TrOOP) expenses for prescription drugs.

I certify that I will not seek reimbursement or credit for this prescription from any insurer, health plan, or government program, including Medicare and Medicaid.

## H COVERAGE LINK PROGRAM

**The Coverage Link Program (Change in Commercial Coverage) provides a free supply of Rubraca in 15-day increments (up to 90 days) for eligible patients who experience a change in commercial insurance status, which includes changing to a new insurer following a job change or switching plans during an employer's annual enrollment period.**

### INDICATIONS

RUBRACA® (rucaparib) is indicated:

- for the maintenance treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy
- for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA.

## SELECT IMPORTANT SAFETY INFORMATION

Myelodysplastic Syndrome (MDS)/Acute Myeloid Leukemia (AML) occur in patients treated with RUBRACA and are potentially fatal adverse reactions. In 2141 treated patients with ovarian and prostate cancer, MDS/AML occurred in 34 patients (1.6%), including those in long term follow-up. Of these, 14 occurred during treatment or during the 28-day safety follow-up (0.7%).

The duration of RUBRACA treatment prior to the diagnosis of MDS/AML ranged from < 2 months to approximately 72 months. The cases were typical of secondary MDS/cancer therapy-related AML; in all cases, patients had received previous platinum-containing chemotherapy regimens and/or other DNA damaging agents.

In ARIEL3, of patients with ovarian cancer associated with a germline and/or somatic BRCA mutation who were treated with RUBRACA, MDS/AML occurred in 9 out of 129 (7%) patients treated with RUBRACA and 4 out of 66 (6%) patients treated with placebo. The duration of therapy with RUBRACA in patients who developed secondary MDS/cancer therapy-related AML varied from 1.2 to 4.7 years.

In TRITON3, MDS/AML occurred in 2 out of 201 patients (1%) with a BRCA mutation treated with RUBRACA. The duration of therapy with RUBRACA in patients who developed secondary MDS/cancer therapy-related AML varied from 1.4 to 2.3 years.

Do not start RUBRACA until patients have recovered from hematological toxicity caused by previous chemotherapy ( $\leq$  Grade 1). Monitor complete blood counts for cytopenia at baseline and monthly thereafter for clinically significant changes during treatment. For prolonged hematological toxicities (> 4 weeks), interrupt RUBRACA or reduce dose and monitor blood counts weekly until recovery. If the levels have not recovered to Grade 1 or less after 4 weeks or if MDS/AML is suspected, refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics.

If MDS/AML is confirmed, discontinue RUBRACA.

Based on findings from genetic toxicity and animal reproduction studies, RUBRACA can cause fetal harm. Advise male patients with female partners of reproductive potential or who are pregnant to use effective methods of contraception during treatment and for 3 months following last dose of RUBRACA. Advise male patients not to donate sperm during therapy and for 3 months following the last dose of RUBRACA. Advise females of reproductive potential to use effective contraception during treatment and for 6 months following the last dose of RUBRACA.

Most common adverse reactions of patients with BRCA-mutated mCRPC treated with RUBRACA in TRITON3 ( $\geq$ 10%, Grade 1-4) were fatigue/asthenia (61%), musculoskeletal pain (53%), nausea (51%), decreased appetite (34%), diarrhea (31%), constipation (31%), vomiting (25%), dyspnea (19%), dysgeusia (18%), edema (18%), abdominal pain (17%), dizziness (16%), weight decreased (16%), rash (13%), headache (12%), peripheral neuropathy (12%), photosensitivity reaction (12%), and urinary tract infection (10%).

Most common select laboratory abnormalities of patients with BRCA-mutated mCRPC treated with RUBRACA in TRITON3 ( $\geq$  25%, Grade 1-4) were increased ALT (68%), decreased neutrophils (67%), decreased phosphate (64%), decreased hemoglobin (60%), increased AST (59%), increased creatinine (56%), increased glucose (45%), decreased lymphocytes (43%), decreased sodium (35%), decreased platelets (34%), and increased calcium (29%).

Most common adverse reactions of patients with BRCA-mutated mCRPC treated with RUBRACA in TRITON2c ( $\geq$  20%; Grade 1-4) were fatigue/asthenia (62%), nausea (52%), decreased appetite (28%), rash (27%), constipation (27%), vomiting (22%), and diarrhea (20%).

Most common laboratory abnormalities of patients with BRCA-mutated mCRPC treated with RUBRACA in TRITON2 ( $\geq$  35%; Grade 1-4) were increased ALT (69%), decreased leukocytes (69%), decreased phosphate (68%), decreased absolute neutrophil count (62%), decreased hemoglobin (59%), increased creatinine (43%), decreased lymphocytes (42%), increased triglycerides (42%), decreased platelets (40%), and decreased sodium (38%).

Most common adverse reactions for patients with BRCA-mutated ovarian cancer treated with RUBRACA in ARIEL3 were ( $\geq$ 20%, Grade 1-4) were nausea (79%), fatigue/asthenia (74%), abdominal pain/distention (48%), constipation (39%), vomiting (37%), diarrhea (34%), stomatitis (28%), rash (45%), dysgeusia (33%), headache (22%) ALT/AST elevation (33%), anemia (41%), thrombocytopenia (35%), neutropenia (22%), nasopharyngitis/upper respiratory tract infection (29%), and decreased appetite (23%).

Most common select laboratory abnormalities of patients with BRCA-mutated ovarian cancer treated with RUBRACA in ARIEL3 ( $\geq$ 25%, Grade 1-4) were increase in creatinine (96%), increase in ALT (67%), decrease in hemoglobin (61%), increase in AST (59%), decrease in platelets (47%), decrease in leukocytes (39%), increase in cholesterol (39%), decrease in neutrophils (38%) and decrease in lymphocytes (33%).

Concomitant administration of RUBRACA with CYP1A2, CYP3A, CYP2C9, or CYP2C19 substrates can increase the systemic exposure of these substrates, which may increase the frequency or severity of adverse reactions of these substrates. If concomitant administration is unavoidable between RUBRACA and substrates of these enzymes where minimal concentration changes may lead to serious adverse reactions, decrease the substrate dosage in accordance with the approved prescribing information.

If concomitant administration with warfarin (a CYP2C9 substrate) cannot be avoided, consider increasing the frequency of international normalized ratio (INR) monitoring.

Full Prescribing Information available at: <https://www.rubracahcp.com>.

For medical information inquiries within the U.S., contact pharma& at [medinfo.us@pharmaand.com](mailto:medinfo.us@pharmaand.com).

You may report adverse events to the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Alternatively, to report an adverse event or reaction, contact pharma& at [pv@pharmaand.com](mailto:pv@pharmaand.com).

To report a product complaint, contact pharma& at [complaints@pharmaand.com](mailto:complaints@pharmaand.com).

