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. A copy of the HIPAA authorization is available upon request.

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 _____

QuickStart Program

Dosage ◯ 300 mg ◯ 250 mg ◯ 200 mg Days supply ☐ 15 days Quantity _____ Refills *(3 max)* _____

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.

Please see Select Important Safety Information on pages 4 and 5.

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 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 and a taxane-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for RUBRACA.

  This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Please see additional Select Important Safety Information on page 5.

SELECT IMPORTANT SAFETY INFORMATION

Read full ISI

Myelodysplastic Syndrome (MDS)/Acute Myeloid Leukemia (AML) have occurred in patients treated with Rubraca, and are potentially fatal adverse reactions. In 1594 treated patients with ovarian cancer, MDS/AML occurred in 32 patients (2%), including those in long term follow-up. Of these, 14 occurred during treatment or during the 28-day safety follow-up (0.9%). 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 a germline and/or somatic BRCA mutation 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 TRITON2, MDS/AML was not observed in patients with mCRPC (n=209) regardless of homologous recombination deficiency (HRD) mutation.

Do not start Rubraca until patients have recovered from hematological toxicity caused by previous chemotherapy (≤ 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.

Rubraca can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings from animal studies. Apprise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for 6 months following the last dose of Rubraca.

For males on Rubraca treatment who have female partners of reproductive potential or who are pregnant, effective contraception should be used during treatment and for 3 months following the last dose of Rubraca. Advise male patients on Rubraca treatment, who have female partners of reproductive potential or who are pregnant to use effective contraception during treatment and for 3 months following the last dose of Rubraca.

Most common adverse reactions in ARIEL3 (≥ 20%; Grade 1-4) were nausea (79%), fatigue/asthenia (74%), abdominal pain/distention (48%), rash (45%), dysgeusia (33%), anemia (41%), AST/ALT elevation (33%), constipation (39%), vomiting (37%), diarrhea (34%), thrombocytopenia (35%), nasopharyngitis/upper respiratory tract infection (29%), stomatitis (28%), decreased appetite (23%), and neutropenia (22%).

Most common adverse reactions in TRITON2 (≥ 20%; Grade 1-4) were fatigue/asthenia (62%), nausea (52%), anemia (43%), AST/ALT elevation (33%), decreased appetite (28%), rash (27%), constipation (27%), thrombocytopenia (25%), vomiting (22%), and diarrhea (20%).

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

Because of the potential for serious adverse reactions in breast-fed children from Rubraca, advise lactating women not to breastfeed during treatment with Rubraca and for 2 weeks after the last dose.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to pharma& at 1-800-506-8501.