

Non-formulary riociguat (Adempas) Inpatient REMS Procedure for Genesis East Pharmacy

PATIENT ALREADY ON RIOCIQUAT (ADEMPAS)

If a physician orders riociguat (Adempas) from the home medication list:

BEFORE VERIFYING MEDICATION ORDER:

- confirm patient is still taking riociguat and the dose used with patient and/or family AND
- For female patients, contact the Adempas REMS program at 1-855-423-3672
 - If after hours and the Adempas REMS is closed, contact the Adempas REMS on the next business day. Use your judgement and verify all other information to avoid disruption of patient's home course.

The pharmacist must make every effort to use the patient's own supply as we do not routinely carry this medication and we do not want a delay in therapy. If the patient did not bring riociguat with them, discuss with patient if there is a family member or friend that can bring the medication to the hospital within 24hrs.

If a patient is unable to provide a home supply or this is a new start, we have an account set up with CuraScript SD Specialty Distribution (phone 877-599-7748; account #53586) for purchasing the drug. Available dosage strengths include 0.5mg, 1mg, 1.5mg, 2mg and 2.5mg tablets in 9 count bottles. Try to avoid splitting tablets to make a dose (i.e. for 1.5 mg dose, give 1 x 1 mg tab and 1 x 0.5 mg tab). In order to complete the order, you will need to provide our Adempas REMS ID (19034) and the NPI or DEA number of an Adempas REMS enrolled provider. Care coordination should be involved early on to ensure patient will be able to continue therapy without interruption when discharged.

MALE PATIENT:

Male patients are not enrolled into the Adempas REMS program. Pharmacist entering the riociguat must write a progress note BEFORE VERIFYING MEDICATION ORDER and include following:

- Name of the **prescriber who is enrolled** in the Adempas REMS program and who is managing the patient at home. If the prescribing physician is NOT available, contact the Adempas REMS program for help in identifying other practitioners on staff who ARE enrolled in the Adempas REMS program and available to help manage the patient admitted on riociguat.

FEMALE PATIENT:

Pharmacist entering the riociguat order must write a progress note BEFORE VERIFYING MEDICATION ORDER and include following:

- **Patient enrollment** into the Adempas REMS program was verified and the Adempas REMS Program Coordinating Center has been notified of inpatient admission.
- Name of the **prescriber who is enrolled** in the Adempas REMS program and who is managing the patient at home. If the prescribing physician is NOT available, contact the Adempas REMS program for help in identifying other practitioners on staff who ARE enrolled in the Adempas REMS program and available to help manage the patient admitted on riociguat.

- Patient's **reproductive status**. If patient has reproductive potential, indicate that **pregnancy test** was obtained and report the date, time and the result. See definition of females who are able to get pregnant at www.adempas.com. If needed, the pharmacist will notify the admitting prescriber that a pregnancy test is required and the pharmacist will enter the order for a one time pregnancy test. Female is of non-reproductive potential if she has not yet entered puberty OR has permanent irreversible infertility (no uterus) OR has gone through menopause defined as not having had a period for at least 12 months for natural reasons or who have had their ovaries removed.
- If positive pregnancy test, riociguat will not be dispensed to the patient. Notify the patient's riociguat prescriber and the inpatient provider of pregnancy status. Pharmacist will discontinue riociguat from the inpatient medication profile and will contact Bayer at 1-888-842-2937 or DrugSafety.GPV.US@bayer.com.
- If patient has reproductive potential, indicate verification of **patient education** about the risk of embryo-fetal toxicity, the need to use effective contraception, to get monthly pregnancy tests, and to inform the prescriber of a pregnancy immediately. Indicate the date when patient counseling was completed and the name of a person who performed the education. If education completion cannot be verified, pharmacist will perform the required patient counseling prior to verifying riociguat order.

Note: Females who are able to get pregnant must use two acceptable forms of birth control during treatment with riociguat and for one month after stopping riociguat. To learn more about acceptable birth control, see the Prescriber and Pharmacy Guide for Adempas REMS at www.adempasrems.com.

PharmNet COMPUTER ORDER ENTRY:

We do have riociguat as a medication order entry but only as the 0.5mg tab (it comes as 0.5mg, 1mg, 1.5mg, 2mg, and 2.5mg tabs). Choose the 0.5mg tab and put the actual dose in the appropriate field. If we will be supplying the medication and the dose is other than 0.5mg, IT to add the appropriate dose and cost information. If the patient will be using his or her own supply choose the 0.5mg strength and type in the correct dose in the appropriate field.

Send an email to Pharmacy Manager to confirm appropriate order entry and charging information. This information will also be used to track patients throughout their inpatient stay.

Follow GHS policy for Patient's Own Medications Inpatient Usage including that patient will not be allowed to self-medicate or keep his/her own medications at the bedside, except under special circumstances.

DISCHARGE

For the female patient, verify and document in the progress note the enrollment in the REMS program.

GHS will NOT dispense any more than a 15 day temporary supply to the patient upon discharge. The pharmacist will print an additional copy of the discharge label, place it on an 8-1/2 X11" sheet of paper and have the patient sign that he received Adempas from the inpatient facility.

Example: I _____ (typed patient's name) have received _____ tablets of _____ mg Adempas from Genesis East Pharmacy on _____ (date).

This information will be given to the pharmacy manager for recordkeeping and confirmation of REMS compliance.

GHS EAST PHARMACY WILL NOT DISTRIBUTE, TRANSFER, LOAN, OR SELL ANY RIOCIQUAT TO ANY OTHER FACILITIES!!

STARTING A PATIENT ON ADEMPAS (RIOCIQUANT) WHILE INPATIENT

MALE PATIENT:

Male patients are not enrolled into the Adempas REMS program. Pharmacist entering the riociguat must write a progress note BEFORE VERIFYING MEDICATION ORDER and include following:

- Name of the **prescriber who is enrolled** in the Adempas REMS program and who is initiating riociguat therapy. If the prescribing physician is NOT enrolled, contact the Adempas REMS program for help in identifying other practitioners on staff who ARE enrolled in the Adempas REMS program and available to help manage the patient who is initiated on the riociguat.

FEMALE PATIENT:

Pharmacist entering the riociguat must:

- Verify that patient has been enrolled into the Adempas REMS program by the prescriber. Patient REMS enrollment must be completed by a provider prior to discharge. In case the enrollment was not completed, pharmacist will notify the prescriber about the REMS enrollment requirement.
- Write a progress note BEFORE VERIFYING MEDICATION ORDER (follow the format listed on the first and second pages for female patients already using Adempas).

Proceed to complete order verification and entry as instructed on the first page for patients already using riociguat.