April 24, 2020

COM-2020-035

Dear provider of healthcare-related services,

On April 8, 2020, we sent a communication (COM-2020-025) notifying that a prior authorization (PA) was implemented for hydroxychloroquine and chloroquine to better manage the utilization of these medications, while providing access to patients who need them and mitigating a potential drug shortage.

In our communication, we highlighted concerns raised by the prescription of hydroxychloroquine and chloroquine for the treatment of COVID-19 in the ambulatory setting without yet being authorized by the Food and Drug Administration (FDA) or recommended by the World Health Organization (WHO) for the treatment of COVID-19. Today, the FDA has issued a Drug Safety Communication highlighting cautions against the use of hydroxychloroquine and chloroquine outside of the hospital setting or a clinical trial due to the risk of serious heart rhythm problems. The FDA's communication includes following **recommendations for healthcare providers**:

- **The FDA recommends initial evaluation and monitoring when using hydroxychloroquine or chloroquine under the emergency use authorization (EUA) or in clinical trials to treat or prevent COVID-19. Monitoring may include baseline ECG, electrolytes, renal function and hepatic tests.**
- **Be aware that hydroxychloroquine or chloroquine can:**
  - **cause QT prolongation**
  - **increase the risk of QT prolongation in patients with renal insufficiency or failure**
  - **increase insulin levels and insulin action causing an increased risk of severe hypoglycemia**
  - **cause hemolysis in patients with Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency**
  - **interact with other medicines that cause QT prolongation even after discontinuing the medicines due to their long half-lives of approximately 30-60 days**
- **If a healthcare provider is considering the use of hydroxychloroquine or chloroquine to treat or prevent COVID-19, the FDA recommends checking ClinicalTrials.gov for a suitable clinical trial and considering enrolling the patient.**
- **Report adverse events or side effects to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.**

Following the FDA communication, we reiterate our recommendation to implement PA for hydroxychloroquine and chloroquine to better manage the utilization of these medications and promote their safe and effective use, as supported by clinical literature.

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It is important to note that:

- Patients who were already receiving treatment with these medications prior to the emergency due to the COVID-19 pandemic and are currently using them will be exempt from this PA.
- This PA will apply for the duration of the emergency or until additional information is published supporting the safety and efficacy of these medications for the treatment of COVID-19 in the ambulatory setting, whichever occurs first.
- The PA criteria are subject to changes as new information becomes available.
- All the evaluations will be completed in less than 24 hours after PharmPix has received the applicable and necessary information to make a determination.

This policy only applies to our members or groups for which PharmPix manages the pharmacy benefit or as stipulated by our clients.

We exhort you to read the full Drug Safety Communication issued by the FDA for additional important details.

The situation with the COVID-19 pandemic is dynamic and constantly changing. We strongly encourage the frequent revision of updated information provided by the FDA, the Centers for Disease and Control Prevention (CDC), and the World Health Organization (WHO), to assure that your practices are consistent with the most updated information.

PharmPix is committed to the health and wellness of our members, and to support you as the COVID-19 pandemic continues to evolve. It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137.

Regards,

Clinical Department

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