April 8, 2020

COM-2020-025

Dear provider of healthcare-related services,

We all have important roles in the front lines of the 2019 coronavirus disease (COVID-19) pandemic that we are facing. As the COVID-19 pandemic continues to evolve, PharmPix is making every possible effort to continue to provide our essential services to assure the use of appropriate medications by the appropriate patients at the correct moment, while also caring for the safety of our employees, their families, and the community in general.

Currently, there are no drugs approved by the Food and Drug Administration (FDA) or recommended by the World Health Organization (WHO) for the treatment of COVID-19. However, it is known that both in the United States and in Puerto Rico, the prescription of hydroxychloroquine and chloroquine has increased. This pattern is probably a result of publications suggesting the possible effectiveness of these drugs for the treatment of COVID-19. Although these drugs are currently under investigation for the treatment for COVID-19, only limited data is available. The efficacy of hydroxychloroquine or chloroquine has not been established, possible safety concerns have been identified, and their optimal dosing and treatment duration for COVID-19 are unknown.

To date, the use of hydroxychloroquine and chloroquine have been authorized by the FDA only in certain hospitalized patients as stated in an Emergency Use Authorization (EUA) issued by the agency on March 28, 2020, and specific criteria must be met in order to access to these medications and used them for the treatment of COVID-19 in certain hospitalized patients. We exhort you to read the full letter of authorization for additional important details such as the scope of authorization, the specific conditions that must be met, etc.

The prescription of hydroxychloroquine and chloroquine for the treatment of COVID-19 in the ambulatory setting is not yet authorized by the FDA and raises various concerns:

- Safety risks, while the efficacy has not been confirmed.
- Shortages that may negatively impact members who need these medications for ongoing treatment of chronic conditions, for which hydroxychloroquine and chloroquine are FDA-approved (e.g. certain inflammatory conditions).

To better manage the utilization of these medications, while providing access to patients who need them and mitigating a potential drug shortage, a prior authorization (PA) has been implemented for hydroxychloroquine and chloroquine. 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.

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- 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 requested information.

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

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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