

## CDC and FDA continue efforts to ensure timely access to front-line treatments for severe malaria

Helping patients gain access to life saving treatments in a timely manner is an important public health issue, and one that the Centers for Disease Control and Prevention and the U.S. Food and Drug Administration routinely work together to address, especially in cases of severe, life-threatening diseases, such as malaria.

According to the CDC, there are approximately 300 cases of severe malaria in the U.S. each year, most of them acquired from travel to countries with malaria. While severe malaria should be treated with intravenous (IV) antimalarial medications, the only FDA-approved IV antimalarial in the U.S., IV quinidine, has been discontinued by its manufacturer and is no longer available. However, through the FDA's Expanded Access program, the CDC and the FDA have collaborated to ensure patients in the U.S. have access to IV artesunate as treatment for severe malaria through the [expanded access investigational new drug process](#).

The FDA's expanded access investigational new drug process allows for access to unapproved treatment outside of a clinical trial setting when there are no comparable or satisfactory therapies available for the treatment of a serious or life-threatening disease or condition. In the case of intravenous antimalarial treatment, the FDA's expanded access regulatory mechanism is being utilized to allow [CDC to provide](#) for the use of IV artesunate, which has not been approved by the FDA, for all cases of severe malaria in the U.S. Although the CDC and the FDA have taken this important step to make this product available to communities nationwide, the ability to quickly transport some of this product to rural areas has provided challenges to clinicians, hospitals, other public health partners and, ultimately, patients.

The CDC and the FDA recognize these concerns and have already taken steps to improve overall access to this important treatment. The CDC has clinicians and Quarantine Station Officers on call 24 hours a day, 7 days a week to provide IV artesunate when needed. IV artesunate is positioned in 18 quarantine stations across the country, strategically located at airports with high flight volumes. Ten stations serve as primary distribution hubs 24/7, and eight additional quarantine stations serve as back-up release sites during business hours. From April 1 through July 31, the CDC supplied 82 courses of intravenous artesunate to 71 different hospitals across the U.S. for patients with severe malaria, with a median delivery time of 5.9 hours. Generally between 2 to 17 hours, delivery times are affected by distance, mode of transport (air or ground), and time of day the request is made. Longer delivery times are associated with lack of onsite staffing at delivery sites after midnight until morning shifts, less frequent overnight flight availability, or long distances from quarantine stations that require both air and ground transport. Nevertheless, CDC is monitoring the distribution of IV artesunate and working to make improvements in its system on an ongoing basis.

We encourage hospitals to have a preparedness plan for patients with fever and recent travel to an area with malaria, including plans for timely diagnosis and treatment of malaria, and a transportation plan for pickup of intravenous artesunate from the nearest airport or prepositioning site. It is also important that hospitals have a stock of oral antimalarials available for initial patient treatment while awaiting intravenous artesunate. CDC has [published guidelines](#) for clinicians on how to treat severe malaria in those circumstances, which include administering oral medications, whether via nasogastric tube in the comatose patient, or in the case of a patient with nausea and vomiting, pretreatment with antiemetics.

The FDA remains committed to using the tools at its disposal to facilitate and expedite the development and review of drugs for the treatment of severe malaria, including continued use of expanded access, as appropriate, when no comparable or satisfactory approved therapies exist for patients with a serious or life threatening disease or condition. The FDA is also working with manufacturers interested in bringing forth therapies that would provide new treatment options for patients with malaria, including severe malaria. Should a new drug application(s) for intravenous artesunate be submitted to the FDA for

evaluation, the agency will ensure timely review and assessment of the safety and effectiveness of the products(s).

CDC and FDA will continue working together with health care providers, clinical and scientific professional organizations, public health partners, transportation carriers, and other stakeholders to assist in the provision of the best care possible for patients with malaria and to address this urgent medical need. Furthermore, the challenges to severe malaria treatment in the U.S. emphasizes the importance of taking medications to prevent malaria and using mosquito avoidance measures when traveling to malaria-endemic areas.

More information:

- [FDA - Expanded Access](#)
- [CDC - Malaria](#)
- [CDC – Availability of Intravenous Artesunate for Treatment of Severe Malaria in the United States](#)

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

CDC works 24/7 protecting America's health, safety and security. Whether disease start at home or abroad, are curable or preventable, chronic or acute, or from human activity or deliberate attack, CDC responds to America's most pressing health threats. CDC is headquartered in Atlanta and has experts located throughout the United States and the world.