



Dear Healthcare Provider:

To facilitate a therapeutic option for treatment of severe malaria in the U.S, the Centers for Disease Control and Prevention (CDC) has been sponsoring an Expanded Access Investigational New Drug program (IND 76,725) since 2007 to provide investigational, intravenous (IV) artesunate to requesting treating physicians for use in accordance with the IND protocol. On May 26, 2020, the Food and Drug Administration (FDA) approved Artesunate for Injection, by Amivas, for treatment of severe malaria in adults and children. Until the FDA-approved artesunate product is marketed and available commercially, CDC will continue to provide investigational, IV artesunate product (manufactured by Guilin Pharmaceutical) under CDC-sponsored IND 76,725/CDC IRB Protocol #7171 to facilitate access to artesunate treatment for patients with severe malaria.

Because the IV artesunate product provided by CDC is not FDA-approved and considered investigational, the use of this product is subject to FDA IND regulations (21 CFR parts 50, 56, and 312). To facilitate timely, nationwide access to investigational, IV artesunate for treatment purpose only (i.e., non-research) and ease the logistical and regulatory burden of individual hospitals from having to procure product, develop a treatment protocol, and obtain FDA permission and Institutional Review Board (IRB) approval, CDC holds an active Expanded Access IND 76,725 filed with FDA that permits CDC's distribution and use of investigational, IV artesunate for treatment of severe malaria at hospitals.

Central IRB approval information:

CDC IRB serves as the central IRB for review of the IND protocol (CDC IRB Protocol #7171) to help reduce the administrative burden on local IRBs and allow timely use of IV artesunate; therefore, hospitals may use CDC IRB's approval of the protocol. CDC IRB determined that use of IV artesunate as described in Protocol #7171 does not constitute human subjects research because it is provided for treatment purposes only (45 CFR 46.102(I)). Therefore, IRB review for compliance with 45 CFR 46 is not needed. Each hospital that receives IV artesunate for treatment of severe malaria under IND 76,725 may use the CDC IRB approval to meet FDA's regulatory requirements for IRB review. Enclosed is a copy of the current CDC IRB approval letter for Protocol #7171 to aid the local IRB's decision and documentation of CDC IRB approval. Due to the volume of hospitals that may be involved in administration of IV artesunate for compassionate, treatment use under IND 76725, it is not feasible for CDC IRB to provide formal IRB authorization agreements. Hospitals that choose to perform their own IRB review rather than utilizing the central IRB review mechanism should be aware that CDC is unable to accommodate requests for changes to Protocol #7171.

Additionally, since the IND protocol for investigational, IV artesunate is solely for treatment and determined to be for non-research purposes), an Federalwide Assurance is also not applicable.

Expanded Access IND requirements:

Informed consent for administration of IV artesunate must be obtained prior to treatment. In requesting, obtaining, and administering investigational IV artesunate, the treating physician is serving as a site investigator and is required to comply with the requirements of the IND (per FDA regulations 21 CFR part 312, subpart D), which includes completing and returning to CDC all case report forms within the protocol. If serious adverse events occur, you must notify CDC within 24 hours by calling the CDC Malaria Hotline at 770-488-7788 (Monday to Friday 9:00am to 5:00pm) or the CDC Emergency Operations Center at 770-488-7100 (after hours). **Your compliance with returning required information to CDC is appreciated and critical to CDC's ability to maintain the IV artesunate Expanded Access IND program and ensure a therapeutic option for severe malaria in the U.S.**

Enclosures: CDC IRB Approval Letter dated August 27, 2020 for CDC IRB Protocol #7171