Expanded Access Policy

Nectero Medical, Inc. is a clinical-stage biotech company pioneering novel therapies to treat aneurysmal disease.

Nectero Medical is conducting a clinical trial for the Nectero Endovascular Aneurysm Stabilization Treatment (Nectero EAST®) System in small- to mid-sized abdominal aortic aneurysms (AAA). The Nectero EAST System is an investigational product. Results of the stAAAble (Nectero EAST® System for Small- to Mid-Sized Abdominal Aortic Aneurysms (AAA) StaBiLization: Evaluation of Efficacy) trial will help to determine the safety and efficacy of this product and are needed before the Nectero EAST System can be made generally available to patients. Patients typically obtain access to investigational products prior to regulatory approval by participating in clinical trials. Nectero Medical encourages participation in their clinical trial (NCT# NCT06001918) based on physician assessment that a patient meets eligibility criteria.

When it is not possible for a patient to participate in a clinical trial and the patient is facing a serious or immediately life-threatening condition for which no other treatment option is available, licensed physicians may seek expanded access to an investigational product on their behalf. Expanded access refers to the use of an investigational product when the primary purpose is to diagnose, monitor or treat a patient rather than to obtain information about safety and efficacy that is generally derived from clinical trials. This access is sometimes referred to as a compassionate use.

Procedure for Requesting Expanded Access

The treating physician requesting expanded access must contact Nectero Medical directly with the basis for the request at NecteroClinical@necteromedical.com. The request should include the physician's contact information to facilitate a timely response by Nectero Medical. We will respectfully acknowledge your request within 10 days of receipt.

Criteria for Expanded Access

Nectero Medical will evaluate and respond to each expanded access request on a case-by-case basis. We will consider the nature of the request, the patient's health status, the available medical and scientific information about the investigational product, the balance of risk and potential benefit to the patient, the availability of investigational product, and the potential regulatory impact.

Nectero Medical's Expanded Access policy will be reviewed regularly as product development continues, and any changes to the policy will be updated on the Nectero Medical website. Posting of this policy by Nectero Medical does not serve as a guarantee of access to investigational Nectero EAST System by any individual patient.