

AMAG Expanded Access Policy

Under the 21st Century Cures Act, the manufacturer or distributor of one or more investigational drugs for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions shall make available its policy on how it evaluates and responds to requests submitted under section 561(b) of the Federal Food, Drug, and Cosmetic Act for provision of such a drug. The following is AMAG Pharmaceuticals, Inc.'s ("AMAG") expanded access policy for investigational drugs that are intended to treat serious diseases:

- (1) **Contact Information.** Please submit any questions or requests regarding expanded access to: amag@druginfo.com.
- (2) **Request Procedures.** Please submit sufficient supporting detail to enable AMAG to evaluate the expanded access request. Please also include contact information about yourself so AMAG may follow-up with you directly.
- (3) **General Criteria.** AMAG will evaluate and respond to each expanded access request that it receives on a case-by-case basis.
- (4) **Anticipated Timing.** AMAG anticipates that it will acknowledge receipt of any expanded access questions or requests within five business days of receipt.
- (5) **Clinicaltrials.gov Hyperlink.** In the event that AMAG begins an investigational drug development program that may qualify for expanded access under the Federal Food, Drug, and Cosmetic Act, this website and policy will be updated with a hyperlink or other reference to the clinical trial record containing the required information about the expanded access for such drug.

As authorized by the 21st Century Cures Act, AMAG may revise this expanded access policy at any time. Additionally, the posting of this policy by AMAG shall not serve as a guarantee of access to any specific investigational drug by any individual patient.