

Spectrum Expanded Access Policy

Spectrum Pharmaceuticals is a commercial-stage biotechnology company with fully integrated commercial and drug development operations, and a leader in hematology/oncology. 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 Spectrum's expanded access policy for drugs that are intended to treat serious diseases:

1. **Contact Information.** Please submit any questions or requests regarding expanded access to the following: EAP@sppirx.com.
2. **Request Procedures.** Requests should be submitted by licensed physicians, and should include sufficient supporting detail to enable Spectrum to evaluate the expanded access request. Please also include your contact information so Spectrum may follow-up with you directly.
3. **General Criteria.** Spectrum will evaluate and respond to each expanded access request that it receives on a case-by-case basis, applying the following guidelines:
 - The physician is experienced enough with the disease and drug class, with IND trial experience, and familiar/ willing to work with local regulatory authorities for single patient use.
 - There must be record of prior utilization of all applicable approved, on-label treatments
 - There is a regulatory mechanism in the country or region to support expanded access
 - There is a plan by Spectrum Pharmaceuticals to market the drug in the country or region from which expanded access was requested
 - There must be documentation of not meeting eligibility criteria for all applicable ongoing clinical trials
 - The request must come from the treating physician
 - The patient must first assess eligibility to applicable ongoing clinical trials utilizing the Spectrum product being requested, for the disease in question
 - There must be adequate supply of the investigational product to meet the needs of the expanded access program without impairing the Spectrum's clinical trials
 - There is a good understanding of the indication for which use is requested
 - The potential benefit must be considered to outweigh the collective potential risks to the patient
 - There must be sufficient clinical data to identify an appropriate dose
 - The program must be compliant with local rules and laws
 - The program should be discontinued as soon as feasible when the drug is approved for the relevant use

4. **Anticipated Timing.** Spectrum will endeavor to acknowledge receipt of any expanded access questions or requests within five business days of receipt.

5. **Clinicaltrials.gov Hyperlink.** This website and policy will be updated with a hyperlink or other reference to the expanded access record on clinicaltrials.gov after such record becomes active.

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