

Expanded Patient Access Policy

Cumberland Pharmaceuticals is a specialty pharmaceutical company committed to delivering medicines that provide an improved quality of care and addresses unmet medical needs for patients. Our development resources are focused on conducting scientific research that evaluates the safety and effectiveness of new medicines for patients with rare diseases. Our clinical trial programs are the primary way to get access to a Cumberland investigational medicine. These clinical trials provide the most effective way to assess how our investigational medicines may prevent and/or treat diseases, and are used to support regulatory approval. Cumberland encourages patients to speak with their treating physicians about participating in a clinical trial, when possible. You can find additional information about Cumberland's ongoing clinical trials by accessing <https://clinicaltrials.gov>. Where enrollment into a clinical trial is not an option, and where all currently available treatment options have been exhausted, an investigational medicine may be provided prior to regulatory approval or commercial availability, under a provision referred to as "Expanded Access" (also commonly called "Compassionate Use") by the U.S. Food and Drug Administration ("FDA").

Expanded Access is a potential pathway for a patient with an immediately life-threatening condition or serious disease or condition to gain access to an investigational drug for treatment outside of a clinical trial when no comparable or satisfactory alternative therapy exists. Per FDA, Expanded Access may be appropriate when all of the following apply:

1. A patient has a serious disease or condition, or a patient's life is immediately threatened by their disease or condition.
2. There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
3. Patient enrollment in a clinical trial is not possible.
4. Potential patient benefits justify the potential risks of treatment.
5. Providing the investigational medical product will not interfere with investigational trials that could support a medical product's development or marketing approval for the treatment indication.

As a general policy, Cumberland will not provide investigational medicines to patients until a dose and schedule has been established for the agent, preliminary data exists that that agent has some evidence of activity in a particular indication, and the investigational medicine is found to be safe as a result of a risk-benefit evaluation.

At this time Cumberland is not currently making any of its investigational medicines available on an Expanded Access basis prior to regulatory approval anywhere in the world. Further, due to the shortage of key raw materials and manufacturing supplies also used in COVID-19 vaccine manufacturing we have limited supplies of all of our investigational medicinal products at this time.



Cumberland may reconsider making one or more of its investigational medicines available through an Expanded Access Program in the future. All requests for Expanded Access must come from a patient's treating physician and will be evaluated and responded to on a case-by-case basis. A patient's treating physician can expect acknowledgement of receipt of their request within 5 business days.

As authorized by the 21st Century Cures Act, Cumberland may revise this Expanded Access Policy at any time. The posting of this policy by Cumberland shall not serve as a guarantee of access to any specific investigational medicine by any individual patient.

If you have additional questions, please speak with your treating physician or contact Cumberland at ExpandedAccess@cumberlandpharma.com.