



Patient Fact Sheet: Expanded Access

What is expanded access?

Sometimes called “compassionate use”, expanded access is a potential way to get access to an investigational medical product, when all the criteria below are met.

- Patient has a serious disease or condition, or whose life is immediately threatened.
- There is no similar or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- Enrollment in a clinical trial is not possible.
- Possible patient benefit justifies the possible risks of treatment.
- Patient taking the investigational medical product will not affect the investigational trials.

What are the risks to me and how am I protected from risk?

Investigational medical products have not yet been approved or cleared by the FDA and the FDA has not found these products to be safe and effective for their specific use. They may, or may not, be effective in the treatment of the condition, and use of the product may cause serious side effects that were not known or expected. FDA reviews the expanded access request and determines whether the expanded access request may move forward. An Investigational Review Board (IRB) assures that proper steps are taken to protect the rights and wellbeing of patients participating in a research study.

Search for possible clinical trials you may qualify for by using [FDA's clinical trials search tool](#) or visiting www.clinicaltrials.gov.

You can also contact the medical product company or patient advocacy organizations to see if they have information on expanded access programs or ongoing clinical trials.

What if I need the medical product on an emergency basis?

For emergency requests after hours and on weekends, your licensed physician should contact FDA's Emergency Call Center at 866-300-4374. Otherwise, they should contact the specific FDA Office (if known) or FDA Patient Affairs at 301-796-8460 or Patientaffairs@fda.hhs.gov.



What costs may be involved?

All the costs involved with the investigational medical product and the medical services associated with its use must be considered. These may not be covered by third-party payers such as private insurance or Medicare.

Will I get the investigational medical product if I meet the criteria?

Not necessarily. Even if you meet the criteria under the law and FDA regulations, the company may not agree to provide the product or your licensed physician or the IRB may not agree that expanded access is appropriate for you. However, on average, FDA determines that the vast majority of all expanded access requests may proceed.

For more information, visit [FDA's Expanded Access webpage](#) or contact Patient Affairs Staff 301-796-8460 or patientaffairs@fda.hhs.gov.