



Physician Fact Sheet: Expanded Access

What is Expanded Access?

Sometimes called “compassionate use”, 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 medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

What are the types of expanded access?

1. Expanded access for individual patients, including for emergency use
2. Expanded access for intermediate-size patient groups
3. Expanded access for widespread treatment use

What is the Licensed Physician’s role in the expanded access process?

- **Determine there are no available clinical trials for the patient.**
Information on clinical trials can be found using [FDA’s clinical trials search tool](#) or visiting www.clinicaltrials.gov.
- **Confirm patient’s current disease or condition qualifies for expanded access.**
Your patient’s disease or condition is either serious or immediately life-threatening with no available comparable or satisfactory alternative available for the patient.
- **Identify the appropriate expanded access request type.**
For questions, contact the appropriate FDA organization or Patient Affairs Staff at 301-796-8460 or patientaffairs@fda.hhs.gov.
- **Confirm industry will provide investigational medical product**
- **Facilitate the process and manage the treatment**
You will be responsible for managing the use of the investigational medical product and the patient's medical care.
- **Provide appropriate reporting back to FDA**

Who should I contact if my patient needs access to an investigational 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 is the process for requesting expanded access for my patient?

Detailed information on the process for requesting expanded access can be found on the FDA's Expanded Access: How to Submit a Request (Forms) webpage.

In general, you will need to:

- **Request the investigational medical product from the company**
- **If the company agrees to provide the investigational medical product, you must:**
 - submit an application to the FDA for expanded access on your patient's behalf
 - obtain review and approval from an Institutional Review Board (IRB)
 - obtain informed consent from your patient for the use of the investigational medical product



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