

Special Access Program (USA)

Compassionate Use Policy for B-Temia's technologies

B-Temia Inc. is a private Canadian company with an ongoing commitment to improve patient outcomes and quality of life in patients suffering from effects of neurological conditions and musculoskeletal disorders.

B-Temia Inc. recognizes that many patients with serious or life-threatening diseases or conditions cannot be treated satisfactorily with the medical products currently authorized for use for their condition. With no other treatment options, these patients may sometimes seek treatment with our Keeogo device. In these cases, if allowed by the applicable local laws and regulations, the treating physician may contact B-Temia Inc. directly to request the Dermoskeleton for their patient, if the patient's condition is outside of the current cleared indications for use.

B-Temia Inc. will evaluate these requests on a case-by-case basis and in a fair and equitable manner considering the available safety and clinical data, and provided that the use of the Keeogo device will not interfere with investigational trials that could support the clinical development or marketing approval of the Keeogo device in relevant treatment indications.

What is “compassionate use”?

Medical professionals use the term “compassionate use” to refer to the treatment of a disease/disorder with an experimental medicine, medical device or product when there are no other treatments available outside of a clinical trial.¹ Other terms used to refer to compassionate use include “expanded access” or “pre-approval access.”

The U.S. Food and Drug Administration (FDA) describes compassionate use as “a pathway for patients to gain access to investigational drugs, biologics and medical devices for serious diseases or conditions. Such investigational drugs/devices have not yet been approved by the FDA and they have not been proven to be safe and effective.”²

Most commonly, compassionate use is the term used when a doctor/clinician is requesting access for a single patient outside of other company-sponsored programs, like clinical trials or an expanded access program.

How does it work?

For an individual patient to receive an investigational medicine, medical device or product in the U.S., the doctor/clinician must make a request to the manufacturer developing the medical device and to the FDA. FDA regulations impose certain requirements for such requests to be granted.¹

FDA must determine that:

- a.) The patient has a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the patient's disease or condition.
- b.) The potential patient benefit justifies the potential risks of the treatment use and those potential risks are not unreasonable in the context of the disease or condition to be treated.
- c.) Providing the medical device for the requested use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise slow the pace of drug development.
- d.) The patient cannot obtain the medical device under another clinical trial or expanded access program.

The patient's physician must also determine that the probable risk to the person from the medical device is not greater than the probable risk from the patient's disease or condition. Beyond these requirements of FDA regulation, companies developing therapies may consider other factors in considering whether to grant requests for individual access, such as the availability of supplies of the medical device.

How can a patient request access?

In addition to the patient, there are three key people or groups involved in the compassionate use process: the patient's doctor, the FDA, and the company manufacturing the medical device.

- a.) The doctor/clinician must review all of the FDA requirements for compassionate use to the medical device treatment with the patient and obtain informed consent. ³
- b.) The doctor/clinician will need to obtain a Letter of Authorization (LOA) from the medical device manufacturer. ⁴
- c.) The doctor/clinician will need to complete an application with the FDA requesting access to the medical device. ⁵ Including an LOA as part of this application allows the FDA to refer to the official medical device FDA clearance (K) number

For additional information, regarding whether or not a patient may be able to gain access to B-Temia's device, is to have the treating physician contact B-Temia Inc. directly at 1 866-443-1010 or info@b-temia.com

1 American Cancer Society.

<http://www.cancer.org/treatment/treatmentsandsideeffects/clinicaltrials/compassionate-drug-use>. Accessed on April 15, 2015

2 U.S. Food and Drug Administration.

<http://www.fda.gov/ForPatients/Other/ExpandedAccess/ucm20041768.htm>. Accessed on April 15, 2015.

3 U.S. Food and Drug Administration. Expanded Access: Information for Physicians.

<http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/ucm429624.htm>. Assessed on April 27, 2015.

4 U.S. Food and Drug Administration. Expanded Access: Information for Physicians.

<http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/ucm429624.htm>. Assessed on April 27, 2015.

5 U.S. Food and Drug Administration. Expanded Access: Information for Physicians.

<http://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/ucm429624.htm>. Assessed on April 27, 2015.

6 *The Wall Street Journal*. The FDA Says It's More Compassionate Than You Think.

<http://blogs.wsj.com/corporate-intelligence/2014/05/05/the-fda-says-its-more-compassionate-than-you-think/?mg=blogs-wsj&url=http%253A%252F%252Fblogs.wsj.com%252Fcorporate-intelligence%252F2014%252F05%252F05%252Fthe-fda-says-its-more-compassionate-than-you-think>. Accessed on April 15, 2015.