

Instructions for Use (IFU)

Blue Note Therapeutics, Inc. Digital Health Information Device (cerena™)

* Images are examples only. Actual screen presentation and layout may differ based on operating system (iOS, Android) and the type and manufacturer of mobile device being used.

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A. INDICATIONS

The Blue Note Digital Health Information Device (cerena™) is an intervention intended to provide physical and emotional health adjunctive to oncology treatments, in order to improve anxiety and depressive symptoms in adult cancer participants.

Cerena™ is a prescription digital therapeutic medical device and must be used under the care of a licensed clinician.

Cerena™ is adjunctive to usual care and should not be used as a substitute for other oncology care (e.g., prescribed medication or treatment), as advised by the patient's treating clinician.

Cerena™ is not for everyone. Cerena™ is intended for cancer patients with moderate to serious anxiety or mild to moderate depressive symptoms.

B. OVERVIEW

The Blue Note Therapeutics Prescription Digital Therapeutic (PDT) Software Application (cerena™) is intended to provide health education directed primarily at physical health. Health education has been widely used as a component of standard of care for the treatment of cancer comorbidities, survivorship programs, and indirect improvement in anxiety and depression. Cerena™ is based on a set of health education modules directed at supporting physical health and wellness as a means to resiliency and improved cancer outcomes. Health education components similar to those administered via the digital intervention are frequently available to patients during supportive care engagement and supporting materials from their oncology team. However, cerena™ administers content in an app-based, private, engaging, on-demand format with reading comprehension assessments in each module.

The digital therapy is a self-directed application launched via a smartphone application and an authentication code provided by a prescribing clinician. The cerena™ application consists of 10 sessions that are completed by the patient once weekly over a 10-week period. The patient should engage with the cerena™ application on a weekly basis to access new articles and complete a brief assessment.

Cerena™ is compatible with most current iOS and Android phones or tablets from most manufacturers running:

- iOS version 14.0 or higher
- Android version 11.0 or higher

Please ensure the mobile device is running an Operating System (OS) version matching those above. If not, please update the device operating system version before downloading and using attune.

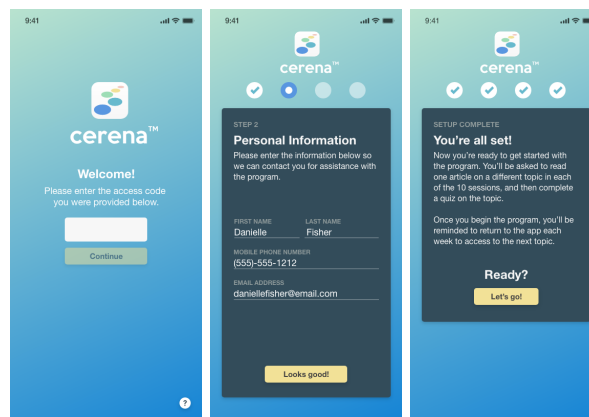
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C. APPLICATION PROCESS FLOW

The main process flow of the application advances the patient through a sequence of 10 sessions that consist of an informational article and a brief assessment.

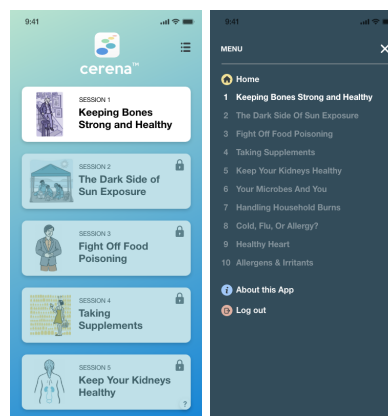
C.1 Onboarding Process

Prior to the patient having access to the first session, the patient must complete an onboarding process that includes activating the application using an access code provided by their prescribing clinician and completing a number of setup steps.



C.2 Sessions list & Main menu

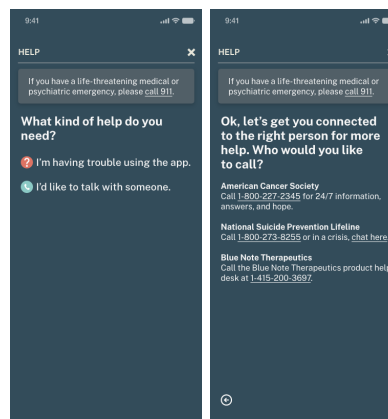
After completing the onboarding process, patients are presented with a list of 10 sessions. The sessions are unlocked every 7 days. Using the menu button, patients may access unlocked sessions, more information about the app, or manually log out.



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C.3 Help Function

A *Help* function, located in the lower right corner, is accessible on every screen. The *Help* function provides additional information if the patient has issues with the app or would like to speak with someone. The *Help* function also directs the patient to call 911 in the case of a life threatening medical or psychiatric emergency.

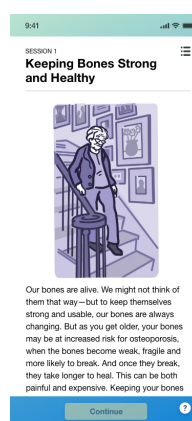


D. SESSIONS

In each session, patients reads content on a general physical health topic and then answer a set of three questions about the topic, based on information in the article.

D.1 Session Article

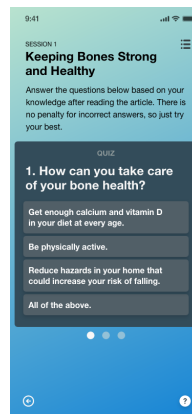
The patient may read the session article on the indicated health topic. Patients must scroll to the bottom of the article to activate the “continue” button.



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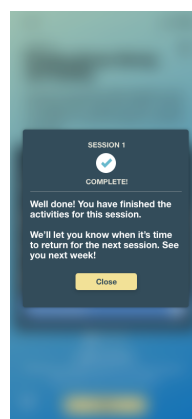
D.2 Session Assessment

The patient is presented with three assessment questions to gauge their understanding of the topic. If they answer incorrectly, they have the opportunity to answer again. The patient must select the correct answer to proceed to the next question.



D.3 Session Complete

Upon completing the assessment, the patient is presented with a “session complete” message, which indicates the end of the session. The message describes how the patient will be notified when the next session is unlocked.



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E Warnings, Precautions and Contraindications

E.1 Warnings and Precautions

Cerena™ is not for emergency use. Patients should call 911 or go to the nearest emergency room in the event of a medical emergency.

Cerena™ is a prescription digital therapeutic medical device and must be used under the care of a licensed clinician.

Cerena™ is adjunctive to usual care and should not be used as a substitute for other oncology care (e.g., prescribed medication or treatment), as advised by the patient's treating clinician.

Cerena™ contains sensitive medical and personal information. Patients must be sure to protect their personal health information by password-protecting smartphones and tablets. Patients must avoid sharing usernames and passwords with others.

Cerena™ has not been clinically tested and may therefore have unknown benefits and risks.

Patients should be advised to contact their prescribing physician if symptoms are not improving or have not improved within a 6-week period and should contact their prescribing physician immediately if symptoms worsen significantly.

E.2 Contraindications

None

E.3 Other

Contact Blue Note at 415-200-3697 or at help@bluenotetx.com for assistance or additional troubleshooting.

Cerena™ has not been cleared or approved by FDA.

Cerena™ IFU has not been cleared or approved by FDA.

The patient should contact their treating clinician for additional resources or recommendations related to the treatment of anxiety and depressive symptoms and/or references made by American Psychological Association.

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