



OUTCOME ASSURANCE PROGRAM/PATIENT

BONE HEALTH

The Eniva Bone Health Outcome Assurance Program is designed to assist patients in achieving bone mass health with the confidence of a money back guarantee for products purchased as part of the program.*

Outcome Assurance Guarantee

The patient should see an improved T-score at the 12-month conclusion of using the Eniva Bone Health Program as compared to their baseline T-score.* If this outcome is not achieved, the patient shall receive a full refund of products purchased as part of the program.

General Overview

- Duration of the program is 12 months.
- The metric for measurement is T-score.
- The approved test methodology is central DXA.[^]
- Standards for bone health and T-score rating are according to the WHO (World Health Organization).
- Patient must comply with product use requirements and guidelines to qualify for the Outcome Assurance Money Back Guarantee.
- Should the patient follow the instructions and guidelines and not see the desired outcome after the 12 months, a full 100% refund will be made to the patient for products purchased as part of the program, including tax and shipping if applicable.
- Eniva Health will refund to the practitioner any product purchases for that patient's product use in the program, including shipping and tax if applicable.
- In the event the patient is a heavy drinker, smoker or takes medications which promote bone loss as a side effect either at the beginning of the program or during, they do not qualify for the Outcome Assurance Guarantee. Patients must share with their healthcare professional any medications they are using at the beginning of the Outcome Assurance Program for eligibility.

Quick Reference Guide – Bone Density Test Results

A T-score identifies a person's bone density by scoring how much higher or lower it is as compared to the bone density of a healthy 30-year old adult.

According to the World Health Organization (WHO):

- T-scores of -1.0 or above are classified as normal bone density.
- T-scores between -1.0 and -2.5 are classified as low bone density and is referred to as osteopenia.
- A T-score of -2.5 or below is classified as severely low bone density and is referred to as osteoporosis.

[^] Note that bone screening tests, such as pDXA (peripheral dual energy x-ray absorptiometry), QUS (quantitative ultrasound) and pQCT (peripheral quantitative computed tomography) cannot be directly compared to central DXA scans. Practitioners with access to these screening test devices may submit a testing methodology for approval for use in the Outcome Assurance Program.

Program Details

Patient is required to purchase products through their practitioner's office and/or using the practitioner's online clinic code in order for the Outcome Assurance Guarantee to be honored by Eniva Health.

1. Patient will provide to their doctor a baseline central DXA scan (or other approved scan) to establish a baseline T-score prior to beginning the Eniva Health Bone Program. Prior tests, up to 30 days of start date, may be used as the baseline score.
2. Patient must provide a final comparative T-score test at the conclusion of the 12-month program or as noted below.
 - a. It is recommended that the patient have another DXA scan taken at the 6-month mark and again at the end of the 12-month time frame to document T-score performance. Patient may skip the 6-month test if desired and only provide the final 12-month test. However, many patients elect to have an intermediate scan conducted.
 - b. Please note, a final central DXA scan must be provided to the practitioner at the conclusion of the 12 months or sooner should goal accomplishment occur prior to the 12 months.

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- c. To ensure consistency of bone scan reporting, it is important the same central DXA machine be used for beginning and ending scans and the same scan protocol followed. It is also important to request confirmation the machine calibration documentation is current. Please confirm and validate these items with your scan provider.
3. Patient will purchase and use as directed the Eniva products listed in the Nutritional Support for Bone/Osteo Health Instructions provided by Eniva Health.
 - a. Products must be purchased monthly and/or an equivalent amount purchased in intervals that will support continued, uninterrupted product use.
 - b. Should purchase history of the patient not support a continued-use pattern at the dosages identified in the instructions, the money back guarantee cannot be honored.
4. The practitioner agrees to document the sale of the products purchased by patient enrolling in the Outcome Assurance Program and keep this information on file for each patient in the event a refund is requested.
5. The practitioner overseeing the patient agrees to review the instructions with the patient prior to product use.
6. At the end of the 12-month program test scores are evaluated. In the event T-scores have not improved, patient shall receive a full refund of monies spent on product throughout the duration of the program.
 - a. This applies only to products identified in the Bone Health program at the dosages specified and does not include other Eniva products that may have been purchased in addition to the Bone Health Program.
7. There will be no consideration of any refund for any patient, for any reason, who chooses to enroll into the program and does not follow the instructions or complete the program as outlined and identified.
8. As the patient has paid the practitioner office for the products, the practitioner office shall refund the monies of the patient, including shipping and tax if applicable, and Eniva Health shall refund the practitioner office.
 - a. Copies of patient invoices shall be required and a refund form be completed for documentation purposes.
 - b. In the event patient has used the practitioner's clinic code for online purchases, Eniva Health will refund monies directly to patient for those purchases made as part of the program. A portion of these monies may be refunded by the practitioner office if a revenue share model is in use.
9. The practitioner may ask the patient to share information with Eniva Health regarding program outcomes in a manner that does not violate patient privacy laws. The patient is not obligated to share this information.

Patient Enrollment in Outcome Assurance Program & Acknowledgement

I, _____, understand the content of this document and would like to enroll in the Bone Health Outcome Assurance Program offered by Eniva Health.

I understand I am required to use daily the Eniva products listed in the Eniva Health "Nutritional Support for Bone/Osteo Health" instructions for 12 consecutive months. I understand I must purchase product through my doctor's office and/or Eniva Health using the clinic code from my practitioner equivalent to the amounts required during the 12 months to ensure uninterrupted use at the dosages specified.

I understand that I am required to have a central DXA scan to establish a bone mass density T-score prior to beginning the program. This test must be conducted within a time period no greater than 30 days prior to beginning the program. This report will be kept on file with my practitioner as a benchmark for tracking my progress. I understand I will have another DXA scan taken at approximately 12 months of product use in order to track my progress. This scan will need to be received and kept on file with my health professional.

I understand that my health professional will document the purchase of all Eniva products for the Eniva Bone Health Program and will keep this information on file in the event a refund is requested. I understand that my healthcare professional will assist me in understanding product use instructions and program guidelines.

At the end of the 12-month program, if my bone mass T-score does not exceed my baseline T-score at the beginning of the program, I shall receive a full refund on the Eniva products purchased which are part of the Bone Health Outcome Assurance Program. This refund shall include shipping and tax if applicable.

Patient Signature: _____ Date: _____

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