leneva®

ALLOGRAFT ADIPOSE MATRIX

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mtfbiologics

Wound Care

General Information

What is Leneva Allograft Adipose Matrix?

Leneva Allograft Adipose Matrix is comprised of adipose tissue which is intended for the replacement of damaged or inadequate integumental adipose tissue matrix in areas of the body where native fat would exist. Leneva Allograft Adipose Matrix may also be used for the reinforcement or supplemental support in underlying adipose tissue matrix as the result of damage or naturally occurring defects. The process utilized preserves the extracellular matrix of the allograft adipose. The resulting allograft serves as a framework to support the cellular repopulation and vascularization at the surgical site.

Where can Leneva be used?

Leneva is injected where fat naturally exists, to replace volume where fat loss occurs. It is commonly used to restore volume in high pressure areas of the foot, as well as areas of the body. Leneva is intended for the replacement of damaged or inadequate integumental adipose tissue matrix. Such clinical applications include, but are not limited to: diabetic foot ulcers, pressure ulcers, tunneling wounds, fat pad reconstruction procedures.

How does Leneva work?

Leneva contains the same collagens, growth factors and extracellular proteins as native fat.[1,2] When injected, Leneva is gradually replaced with the body's own fat cells over the subsequent twelve weeks. Post injection, new blood vessels and fat cell maturation result in volume restoration.[1,3]

In what site of care can Leneva be used?

Leneva can be used in the outpatient, inpatient hospital and physicians office setting. Reimbursement will vary depending on the location and diagnosis and procedure. Please reach out to your wound care consultant for more information.

What is the FDA regulatory status for Leneva?

Leneva is regulated as a human cell/tissue product (H/CTP) under 21 CFR Part 1271 and Section 361 of the Public Health Services Act. FDA registration listing can be found on the company website at https://www.mtfbiologics.org/licenses-certifications or can be provided upon request.

Where does Leneva come from?

Leneva is procured from donated human adipose tissue. The tissue is minimally manipulated and aseptically processed to ensure the safety and quality of the resulting allograft.

How is Leneva processed?

Leneva is derived from the hypodermis/adipose layer of human skin. Once isolated, the tissue goes through a series of processing steps including cutting, delipidating, decellularization, disinfection, and packaging. The entire process is performed aseptically in ISO certified clean rooms to ensure the quality of the resulting allograft.

What types of wounds can Leneva be used on?

Leneva can be used anywhere on the body where adipose tissue naturally occurs.

Does Leneva have fat cells or any other living/devitalized cells?

No, as part of the processing steps, the endogenous cells of the donated adipose tissue are removed to prevent any graft-host rejection or tissue necrosis.*

Is Leneva sterile?

As part of the processing steps the tissue undergoes a chemical disinfection step. In addition, the resulting allograft is tested to confirm no evidence of microbial growth, complying with the requirements of USP <71> Sterility Tests. We do not subject the allograft to additional terminal sterilization procedures.

How do I store Leneva?

Leneva should be stored at ambient temperature.
No refrigeration or freezing is required.

What are the indications for Leneva?

As an HCT/P Leneva does not have specific indications. It is intended for homologous use and should be used for the replacement or augmentation of damaged or inadequate integumental adipose tissue.

Who can Leneva benefit?

Leneva can help patients that need to replace adipose tissue as a result of damaged or naturally occurring defects.

What type of fat is Leneva sourced from and what does it repopulate as?

The source tissue for Leneva comes from various anatomical locations. As a result of the process, the host adipose cells are removed and the resulting allograft is the same irrespective of source location.

What is the mechanism of action of Leneva?

In vitro and in vivo pre-clinical studies have been performed to investigate the mechanism of action of Leneva. These studies have shown that Leneva provides a scaffold for host cells to infiltrate, proliferate, and mature leading to adipogenesis and angiogenesis.[1] These results were published in a peer-reviewed article which can be provided by request by your Wound Care Consultant.

Is there clinical data on Leneva?

The safety and remodeling over time of Leneva in human patients was shown in a clinical study, where no severe adverse events were reported and injected Leneva was completely remodeled into native fat by 6 months.3 This and other relevant published peer-reviewed clinical articles, as well as clinical case summaries, can be provided by request to by your Wound Care Consultant.

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How to Use Leneva

How do I prepare Leneva?
Follow the instructions for use provided in the Leneva package insert and reference the available technique guide, available at www.mtfbiologics.org.

How do I inject Leneva?
Injection technique may vary from patient to patient based on procedure and location. Prior to injection, aspirate the syringe to ensure leneva is not injected into a blood vessel. During injection, a fanning technique is recommended in order to evenly spread out the tissue for optimal integration. It is also recommended to inject the tissue in small pearls for even distribution across the injection plane.

Should I offload after injecting Leneva?
Offloading is recommended after injecting Leneva. Patients are commonly offloaded for two to four weeks. Use preferred offloading method based on your clinical discretion.

Can I use Leneva with anesthetics?
Yes, Leneva can be used in conjunction with anesthetic. The anesthetic should be injected separately from Leneva. They should not be mixed together. The use of anesthetics is based on physician discretion and precaution should be taken for patients with potential allergies.

How much Leneva should I inject?
Injection volume will vary patient to patient based on procedure, location, and desired outcome. Consult your MTF Biologics representative for case-specific clinical data and injection volumes.

What size needle should I use?
Leneva has been formulated to be used with a 20G needle or larger bore needle/cannula. The use of a smaller bore needle may result in clogging of the needle.

How often do I need to inject?
Frequency of injection is up to the clinician's discretion and may vary patient-to-patient. In vivo data indicates that Leneva is populated with mature adipocytes and volume normalizes by 12 weeks.[1] At that point, re-injection for volume adjustments may be made.

How long do I have to use Leneva after opening?
Leneva should be used within 2 hours following preparation per the package insert and technique guide.

Is there a pre- and post-procedure protocol for the use of NSAIDs such as ibuprofen, aspirin, etc. with the use of Leneva?
There is no established protocol on NSAIDs, but some clinicians avoid their use post-op in order to not inhibit the natural acute inflammation that is linked to cell recruitment and infiltration. The clinical benefit of this has not been evaluated.

What comes in the Leneva box?
The 1.5cc graft size of Leneva is provided with an accessory kit including an additional empty 3cc syringe and one Luer winged adapter. Per the package insert and technique guide, the graft should be prepared using the empty syringe and transferring back and forth through the winged adapter.

The 3cc graft size of Leneva is provided with an accessory kit including three empty 3cc syringes, a Luer winged adapter, and a Luer lock adapter. Per the package insert and technique guide, the graft should be prepared by transferring to an empty 3cc syringe and then transferring back and forth between the winged adapter and another empty 3cc syringe. The additional 3cc syringe and Luer lock adapter are provided for allocation into smaller volumes if needed.

What is the post injection care procedure?
It is recommended to provide offloading for a minimum of two weeks with footpads, orthotic balancing, and stiff-soled recovery shoe or walking boot, depending on the severity of the atrophy and co-morbidities. If there is an open wound, it is recommended to offload the wound pressure until there is closure of the ulceration. Doctors should use professional discretion and adjust the protocol accordingly.

What to Expect

How long does Leneva last?
Clinical data shows retention of volume up to 6 months post-injection.[3] It is recommended to re-evaluate the injection site as needed.

How does the new fat act in the body?
The remodeled adipose will act in the same manner as the patient's native adipose.

How fast does Leneva work?
In vivo data indicates that Leneva is populated with mature adipocytes and volume normalizes by 12 weeks.[1]

Does Leneva migrate after injection?
Some migration is possible. This will vary based on patient, injection location, and external pressures. Offloading is recommended when applicable to help reduce external pressures.

Will the fat keep growing?
Final tissue volumes higher than what was originally injected have not been observed in any preclinical and clinical studies thus far. In most cases there is a slight reduction in the original volume which then normalizes by approximately 12 weeks.[1]

Will I see a change in volume after the initial injection?
In the weeks following the initial injection some volume reduction is expected. This is due to release of the water component of the graft as it incorporates. Following this initial reduction, the volume may increase as the patient's cells create new fat tissue.

Will there be an inflammatory response to Leneva?
As with any procedure, there is potential for swelling, tenderness, redness, bruising, pain or irritation at the procedure site during the immediate post-procedure period. Some acute inflammation post-injection will likely occur which is necessary for cell recruitment and is a natural part of tissue remodeling.

What are the possible adverse effects?
Possible adverse effects using human adipose include, but are not limited to:

- Anaphylaxis or other allergic response (e.g., urticaria)
- Local or systemic infection
- Specific or non-specific immune response to some component of the graft
- Discoloration of the skin may occur at the procedure site

As with any procedure, there is potential for swelling, tenderness, redness, bruising, pain or irritation at the procedure site during the immediate post-procedure period. In addition rare allergic reaction have been reported.

Reimbursement

How is Leneva reimbursed?
Reimbursement will vary based on diagnosis, procedure and location. Use the MTF provided reimbursement and coding guide as a reference.

Can I use Leneva in my office?
Yes. Due to the injectable nature of Leneva there is no Medicare reimbursement in the office setting, however MTF offers specialized office pricing to reduce costs and help with the patient self-pay approach. Ask your wound care consultant for more information on this specialized office program.

Can I use Leneva in the OR?
Yes, Leneva can be injected in the OR setting. Please reference the MTF provided reimbursement and coding guide for additional guidance on coding and reimbursement.

References

1. Kokai LE, et al. Injectable Allograft Adipose Matrix Supports Adipogenic Tissue Remodeling in the Nude Mouse and Human [published correction appears in Plast Reconstr Surg. 2019 Jul;144(1):264]. Plast Reconstr Surg. 2019;143(2):299e-309e. doi:10.1097/PRS.0000000000005269
2. Alder SC, Kent KJ. "Enhancing wound healing with growth factors. Facial Plast Surg Clin North Am 10 (2002): 129-146.
3. Kokai LE, et al. Clinical Evaluation of an Off-the-Shelf Allogeneic Adipose Matrix for Soft Tissue Reconstruction, Plastic and Reconstructive Surgery - Global Open: January 2020 - Volume 8 - Issue 1 - p e2574 doi: 10.1097/GOX.0000000000002574

*MTF Biologics data on file

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