# Ethnocare Overlay Reimbursement Guide

### For Transtibial and Transfemoral Applications

### HCPCS Code: L5657 (Effective April 1, 2026)



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## Product Overview

The **Ethnocare Overlay** is an innovative prosthetic interface that dynamically adjusts socket fit in response to residual limb volume fluctuations and activity level changes, without requiring users to remove their prosthesis.

Designed to be worn **over the liner and within the existing socket**, the Overlay's **breathable textile structure** integrates an **air expansion system** along the posterior, medial, and lateral aspects of the limb. This system ensures optimal alignment, consistent contact, and targeted volume accommodation.

Users can easily control fit and comfort using a **built-in proximal pump and release valve**, and may also employ an external pump for faster inflation.. The interconnected air cells distribute pressure where needed, filling only the necessary voids for a **secure, uniform fit**. It serves as an effective alternative to prosthetic socks, adjustable sockets, and internal socket padding by **filling voids*, improving fit*, enhancing suspension*, relieving pressure points (especially at the distal end), and reducing potential**

**skin irritations and friction**. This dynamic system offers precise, user-controlled volume management superior to traditional methods.

*Badaire, P., Robert, M. T., & Turcot, K. (n.d.). The Overlay: A solution for volume variations in transtibial amputation. (Cirris), Université Laval. https://hubs.ly/Q02BZC570

*Ethnocare. (2023). Clinical Evaluation Report Overlay. https://hubs.ly/Q02BVPxF0

### Model Information

| Limb Type | Model Number Format | Example |
|---|---|---|
| Transtibial | OVXX-YY-Z *(XX=circumference; YY=length; Z=side)* | OV-23-SH-R |
| Transfemoral | OVTF-XX-YY-ZZZ *(XX=circumference; YY=length; ZZZ=suspension)* | OVTF-LG-32-PIN |

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## Intended Use

The Ethnocare Overlay provides **adaptive, real-time volume management** for individuals experiencing residual limb volume fluctuations that affect prosthetic socket fit, comfort, or function.

**Key Indications:**

- **Volume Fluctuations:** The patient experiences significant fluctuations in residual limb volume throughout the day, resulting in poor socket fit and challenges in maintaining proper socket fit during activities of daily living. This often leads to a lack of total contact between the limb and the socket, causing discomfort and instability, resulting in an improper gait and risk of falls.

- **Non-Uniform Volume Fluctuation:** The patient's limb volume variation is not uniformly distributed, further complicating the fit and comfort of the prosthesis.

- **Traditional Volume Management Methods:** The patient has been unable to effectively manage socket volume using traditional methods, such as appropriately adding or removing socks in a timely manner.

- **Cognitive or Dexterity Issues:** The patient has difficulty managing sock ply changes due to dexterity or cognitive issues. They struggle with adding or removing socks in a timely manner and require a more straightforward, adaptive solution to manage volume variation.

- **Difficulty Donning Prosthesis:** The patient reports significant difficulty donning the prosthesis. The patient frequently struggles to properly seat the limb into the device, resulting in an improper gait and multiple falls over the past three months.

- **Bell Clapping:** The patient experiences a loose fit at the distal portion of the residual limb within the socket, while the proximal portion fits snugly. The patient needs targeted cushioning to reposition the bony anatomy and accommodate distal limb volume.

- **Limb Sensitivity:** The patient has sensitive areas on the limb, making socket fit challenging. There’s a need for targeted cushioning to offload pressure from sensitive areas and apply it to pressure-tolerant ones.

- **Weight Fluctuations:** The patient has undergone significant weight changes due to medical conditions, medications, or other factors, which affect the volume and shape of the residual limb.

- **Transitional Fit Issues:** The patient is transitioning between different prosthetic sockets or equipment and needs a temporary solution to manage volume fluctuations during the adjustment period.

- **Post-Surgical Volume Changes:** The patient is in the post-operative phase and is experiencing rapid volume changes in their residual limb due to edema or

muscle atrophy. Wearing an Overlay may help the patient stay comfortable and use their prosthesis as their limb changes post-op, and possibly reduce the need for additional fittings for check sockets, as the Overlay can accommodate those volume changes.

- **Skin Irritation and Breakdown:** Over a period since delivery, the patient has repeatedly experienced skin abrasions and persistent erythema that take longer than 20 minutes to resolve post-socket use. This repeated skin irritation can inhibit healing and potentially lead to the development of open sores.
- **Active Patients (K4):** The patient is very active (K4) and needs a more adaptable solution to accommodate the dynamic volume changes during physical activities. Traditional methods do not allow effective management of socket volume.

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## Clinical Benefits:

### 1. Enhances Gait Efficiency and Reduces Compensatory Movements

Supported by peer-reviewed findings (Badaire et al., 2024), the Overlay may help users achieve gait mechanics closer to those of healthy individuals by improving limb stability, reducing compensatory strategies, and supporting more consistent limb alignment throughout the gait cycle.

### 2. Improves Stability Across Sitting, Standing, Walking, and Transitions

As limb shape changes between weight-bearing and non-weight-bearing positions, discomfort and instability often occur. The Overlay adapts to these shape changes, providing improved comfort and stability in dynamic daily activities such as standing from a seated position, walking, driving, and prolonged sitting.

### 3. Reduces Fall Risk Through Consistent Pressure Distribution and Alignment

Poor socket fit leads to instability and increased fall risk, particularly for older adults, K3–K4 users, and medically complex individuals. By providing consistent, even pressure distribution throughout the socket, the Overlay helps improve alignment, gait symmetry, and user confidence during walking and transfers.

**4. Maintains Total Contact and Enhances Limb–Socket Stability**

Residual limb volume fluctuates significantly, which can compromise total contact and lead to pistoning, rotation, instability, and inefficient gait patterns. The Overlay's compressible air-expansion system fills voids and stabilizes the limb within the socket, maintaining more uniform contact and reducing unwanted movement.

**5. Minimizes Pistoning and Rotational Movement Inside the Socket**

Pistoning and rotation contribute to instability, skin breakdown, poor suspension, and energy-inefficient gait. By restoring total contact and dynamically filling voids, the Overlay substantially reduces vertical displacement and rotational motion, thereby enhancing suspension and stability.

**6. Reduces Skin Irritation, Friction, and Pressure Points**

By using targeted air-based contouring to offload pressure from sensitive regions and distribute load to pressure-tolerant tissue, the Overlay reduces localized skin irritation, shear forces, and repetitive friction. This benefit is particularly important for patients with vascular disease, diabetes, thin or fragile skin, or chronic sensitivity.

**7. Provides Targeted Distal-End Support ("Bell Clapping" Correction)**

For patients experiencing distal looseness and proximal tightness, the Overlay offers targeted distal volumetric fill and cushioning. This improves distal-end contact, reduces end-bearing pain, and repositions bony anatomy to improve fit, comfort, and gait quality.

**8. Reduces Shear Forces During Donning and Throughout the Day**

Adding socks increases the thickness that must be forced into the socket, creating friction and shear. Because the Overlay is inflated after the limb is inserted into the socket, shear is minimized during donning and throughout the day, helping prevent irritation and tissue breakdown.

**9. Enables In-Socket Volume Adjustment Without Removing the Prosthesis**

Traditional volume-management methods require repeated doffing of the prosthesis to add or remove socks, which is disruptive, imprecise, and impractical for many patients, especially those with cognitive, dexterity, or time constraints. The Overlay allows precise, real-time volume accommodation without doffing, helping maintain functional independence and consistent prosthesis use throughout the day.

### 10. Accommodates Systemic Fluid Fluctuations (Dialysis, Chemotherapy, Cardiac/Renal Patients)

Patients undergoing dialysis, chemotherapy, or receiving medications that affect fluid retention often experience significant limb-volume variability. The Overlay is uniquely capable of adapting immediately and accurately to these fluctuations, reducing instability and maintaining functional socket fit in populations where daily variability is pronounced.

### 11. Improves Residual Limb Alignment

Consistent circumferential pressure from the air-expansion system supports correct limb alignment, reducing compensatory motions and alignment-related discomfort.

### 12. Extends Socket Lifespan by Compensating for Daily and Progressive Limb Changes

Daily fluctuations, long-term atrophy, and changes in the residuum often require frequent socket modifications, internal padding adjustments, or full socket remakes. The Overlay compensates for these variations, delaying the need for adjustments or remakes and helping preserve socket comfort.

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## HCPCS Coding and Reimbursement

**New HCPCS Code: L5657**

Effective Date: October 1, 2025
Long Description:

Addition to lower extremity prosthesis, manual/automated adjustable air, fluid, gel or equal socket insert for limb volume management, any materials

**Short Description:**

Add low ext man aut vol any

**Allowable Status: $306.32**

CMS established allowable pricing in the Second Biannual 2025 HCPCS Coding Final Determinations and the 2026 fee schedule allowable for L5657 will be $306.32 effective April 1, 2026

## Quantity Dispensed Justification

**Two L5657 inserts** are necessary because the device's Instructions for Use require **daily cleaning** with soap and water and specify that the insert **may only be worn when completely dry**. The mandated cleaning process—removal from the liner, hand-washing, thorough rinsing, towel-blotting, and air-drying without heat—results in extended drying time during which the insert cannot be used. To maintain proper hygiene, prevent skin breakdown, and ensure uninterrupted prosthetic use, a second insert is required while the first is being cleaned and dried. This mirrors established medical necessity for other similar insert codes (L5654, L5655, L5656, L5658, L5661, L5665, L5673, L5679, L5681, L5683) and devices like liners (L5769), where dual sets are standard to meet hygiene and wear-time requirements.

**Care and Maintenance:**

**The Overlay IFUs indicate the insert requires regular cleaning and can only be used when completely dry. Consequently, as with other inserts** (eg *L5654, L5655, L5656, L5658, L5661, L5665, L5673, L5679, L5681, L5683* ) **the Overlay is necessary to be dispensed in a quantity of 2 to allow for hygiene purposes.**

**From Instruction For Use:**

**10. CLEANING, MAINTENANCE AND STORAGE:**

**10.1. Cleaning of the device :**

1) Remove the device from the liner.

2) Be sure the integrated pump hole is covered when exposed to fluid (i.e. covering with a finger). Clean the device once a day only with approved cleansing products including neutral soap or mild detergent that is pH balanced, fragrance, bleach and dye free.

Clean the device in warm water 30°C (86°F)

**NOTICE!** Do not put in the washing machine and do not wring out the device to avoid damage.

3) Rinse the device thoroughly with clean warm water to remove all soap residues.

**NOTICE!** Do not expose the integrated pump to water.

4) Insert a towel into the device and air dry.

**NOTICE!** Do not place it in a dryer or use any other heat source for drying.

5) The device can be used only when completely dry.

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## Need for Regular Replacement

**The L5657 insert is positioned within the prosthetic system in a way that exposes it to the same mechanical and environmental stresses that drive six-month replacement for comparable codes.**

### Mechanical and Functional Wear

- Daily loading and shear forces gradually compress and fatigue the insert's materials, reducing its ability to provide consistent structural support within the socket system.
- Loss of mechanical integrity over time can compromise suspension, alignment stability, and gait efficiency, even without direct skin contact.

### Hygiene-Driven Degradation

- The manufacturer's instructions require daily washing, thorough rinsing, and air-drying only when completely dry, which accelerates material breakdown.
- Repeated moisture exposure and drying cycles affect elasticity, bonding, and internal structure, similar to other inserts that are replaced every six months.

### System-Level Fit and Safety

- Even without touching the skin, a worn insert can alter socket fit, increase pistoning, and create instability that indirectly raises the risk of skin irritation or breakdown elsewhere in the interface.
- Maintaining consistent prosthetic function requires timely replacement of all components that influence fit and suspension—not only those in direct skin contact.

### Comparable Insert Codes with Established Six-Month Replacement

The following codes are widely recognized as requiring semiannual replacement due to similar wear patterns, hygiene requirements, and functional roles within the prosthetic system:

- L5654

- L5655
- L5656
- L5658
- L5661
- L5665
- L5673
- L5679
- L5681
- L5683

These components experience the same types of mechanical stress and hygiene-related degradation that justify a six-month interval for L5657.

Clinical Impact of Not Replacing at Six Months

- Reduced suspension and stability
- Increased pistoning and altered gait mechanics
- Higher risk of secondary skin issues due to poor system alignment
- Premature wear of other prosthetic components

A predictable six-month replacement cycle ensures the prosthesis continues to function safely and effectively as a unified system.

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## Billing Guidance

**Billing Tips:**

1. Ensure the L5657 HCPCS code has been added to the Payer's fee schedule and an allowable is established.
2. **Advance Beneficiary Notice (ABN):** Obtain when coverage is not expected, particularly for uses other than daily volume management.

ABN reason: "Medicare may not pay because the item or service is not considered medically reasonable and necessary for the diagnosis or treatment of illness or injury."

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## Clinical Documentation Guidance

**Refer to our complete Medical Necessity Justification Letter Example Here**

Adapt as appropriate for your patient's specific situation:

1. The patient experiences **daily limb volume fluctuations**, resulting in socket instability and poor suspension.
2. **Non-uniform volume changes** cause inconsistent fit and discomfort.
3. Traditional methods (e.g., sock ply adjustment) are **ineffective or impractical**.
4. The patient has **cognitive or dexterity limitations** preventing effective manual volume management.
5. The patient experiences **difficulty donning** the prosthesis and maintaining total contact.
6. **Bell clapping** occurs due to distal looseness; targeted pressure redistribution is needed.
7. **Sensitive limb areas** require localized cushioning and offloading.
8. The patient has **recent weight or post-surgical volume changes**.
9. The patient is **transitioning between sockets** or experiencing **skin breakdown** from poor fit.
10. The patient is **highly active (K4)** and requires real-time volume adaptation for safety and performance.

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## Physician Documentation Checklist

1. States medical need for a **volume management system beyond socks**.
2. Documents the **expected medical benefit** the patient will receive by the implementation of a separate volume management system.
3. **Prescribes** the volume management system addition.

## Prosthetist Documentation Checklist

1. General & Amputation Information

2. Medical History- If Patient experiences daily volume fluctuations due to a medical condition, be sure to document that fact.

3. Daily Life:  Physical Environment, Support People, Activities, Challenges- Document how volume changes impact this patient? Whether the patient navigates in an environment where they are unable to remove the prosthesis to adjust sock ply, document that fact.

4. Patient Goals for Prosthetic service

5. Prosthetic History

6. Examination of Existing Prosthetic

7. Physical Evaluation: Gait, Residuum, Measurements, Outcome Measures

8. Assessment and rationale:
    a. Why was the Overlay chosen?
    b. What alternatives were considered and why were they inadequate?
    c. How does it address the patient's medical necessity?
    d. Care and maintenance requirements. Why are 2 dispensed?

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## Potential Indications for Coverage

- Daily volume fluctuations of the patient's residual limb
- Progressive and continuous changes to the shape and size of the residual limb
- Treatment of a specific fitting issue
- Resolution of socket fit issues when the beneficiary isn't eligible for a replacement socket

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## Prior Authorization

- Ensure the code is on the Payer Fee Schedule and learn whether the payer has established its own allowable.

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## Proof of Delivery

Include the following on the signed proof of delivery:

- Manufacturer: **Ethnocare**
- Model number and part number
- Serial number (if applicable)
- Brand name and HCPCS code: Overlay TT or TF

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## Contact Ethnocare Reimbursement Support

For assistance with coding, documentation, or payer communication:
📧 **Ethnocare**

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