

## Example of Medical Necessity Letter for Ethnocare's Overlay

### Introduction

I am writing to request the Ethnocare Overlay for my patient, [Name of the Patient], who presents with the following relevant diagnoses:

Type of amputation:

Activity Level:

Additional patient's relevant information:

This letter outlines the medical necessity of the Ethnocare's Overlay and provides detailed information on [Patient's Name]'s condition and the anticipated benefit of wearing an Overlay.

### Medical Necessity

This request is medically necessary because (Include all applicable):

- **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.

This illustration is intended to be customized and/or revised specifically for the case being submitted for approval.

- 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.

## **Justification**

The Overlay is a prosthetic device that uses air to allow users to manage changes in limb volume and address socket fit issues. It is worn over the actual liner and slid inside the existing socket of the patient. As such, it can be retrofitted into the patient's existing prosthetic equipment with minor / no modification.

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.

\*Badaire P, Robert MT, Turcot K. The Overlay, a New Solution for Volume Variations in the Residual Limb for Individuals with a Transtibial Amputation. *Sensors*. 2024; 24(14):4744. <https://doi.org/10.3390/s24144744>

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

\*\*\*Ethnocare. (2023). Evaluation Overlay [Case study] [https://hubs.ly/Q02\\_NjdX0](https://hubs.ly/Q02_NjdX0)

The overlay integrates an air expansion system that enables adjustments to predetermined areas in the socket, ensuring proper contact and comfort throughout the day. A built-in pump and release valve enables the patient to effortlessly and precisely self-manage the fit quality of their socket by inflating or deflating the air expansion system. This allows for precise adaptation to the volumetric status of their limb. The patient can adjust the fit of their prosthetic socket to accommodate limb volume fluctuations and changes in activity level throughout the day, maintaining an appropriate socket fit without needing to remove the prosthesis.

It is well-documented that the volume of a residual limb changes significantly over time post-doffing, with substantial changes often occurring within the first 5 minutes. These changes can vary greatly between users, and even for the same user, the rate of volume change can differ from day to day. This variability makes predicting the post-doffing volume of the residual limb challenging.

Prosthetic socks, which require donning and doffing, offer an imprecise solution for volume management. However, with the Overlay, patients do not need to don and doff the prosthesis, resulting in more precise and predictable volume management.

Since certain regions of the limb experience greater variability in volume, the use of air, a compressible and movable fluid, effectively compensates for these fluctuations and creates a uniform fit inside the socket. This targeted adjustment allows for much more effective volume management compared to sock application. It can be adjusted immediately when the patient recognizes the need, thereby proactively preventing limb irritation.

The Overlay can be inflated by the wearer once the limb is inside the socket, eliminating the need to force additional thickness into the socket, as with traditional socks. This significantly reduces the skin shear patients typically experience during socket donning.

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The integrated air expansion system, located on the product's posterior, medial, and lateral aspects, ensures proper surrounding and alignment of the limb inside the socket. It minimizes the risk of improper residual limb placement within the socket. These different elements enhance patient gait and stability within the socket, thereby reducing the likelihood of tripping and falling.

Consequently, the Ethnocare's Overlay is reasonably expected to prevent the onset of such issues: [insert patient specifics such as : offload pressure from sensitive areas and apply it to pressure-tolerant ones]

The addition of Ethnocare's Overlay is reasonably expected to assist this patient in achieving or maintaining maximum functional capacity in performing daily life activities (ADL's). [Insert specifics here such as : To date, our clinic has successfully fitted 15 patients with this technology for similar indications. Patient's Physiatrist informed about this technology and has observed positive outcomes in 11 of his patients who have benefitted from the Overlay.]

Should you need any further information from my records, please do not hesitate to reach out.

Kind regards,

### **Key considerations for preparing your letter**

- Document previous treatment failures encountered by the patient.
- Emphasize the advantages of Ethnocare's Overlay over standard treatment protocols.
- Reference previous successes with the implementation of Ethnocare's Overlay.
- Include endorsements from physical or occupational therapists that validate patient experiences and address specific clinical issues.
- Address psychological factors pertinent to the patient's condition and the selected treatment.
- Provide detailed information that a remote claims processor might not have access to.
- Include references to discussions with other treating physicians or relatives of the patient.

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## **Proven Results**

A \*case study conducted in Canada that included 24 transtibial patients indicates the Overlay demonstrated effective volume management and benefits for patients, including: **Improved socket fit; enhanced cushioning; pain reduction; ease of use** compared to the traditional use of prosthetic socks; and **overall improvement in user comfort and satisfaction.**

Significant results over traditional methods of socket volume management include:

1. Users reported a **↑24% improvement in socket fit** with the Overlay
2. Users experienced **↑46% better cushioning** when using the Overlay
3. Patients indicated their **pain sensation decreased by ↓24%** when wearing the Overlay
4. Users found the Overlay **↑52% easier to use** than adding prosthetic socks.

\*Ethnocare. (2023). Evaluation Overlay [Case study] [https://hubs.ly/Q02\\_NjdX0](https://hubs.ly/Q02_NjdX0)

## **Research Article**

An independent peer-reviewed article published in *Sensors* found that the Overlay seems to provide a better quality of life and is more suitable for the needs of transtibial amputees during functional tasks (e.g., walking and sit-to-stand tasks) than Prosthetic Folds. The study highlighted several benefits of the Overlay, including a reduction in pain and compensatory strategies, as well as improvements in gait—helping users achieve a gait closer to that of a healthy individual—stability, socket fit, and comfort compared to the Prosthetic Fold (Ply).

Badaire, P.; Robert, M.T.; Turcot, K. The Overlay, a New Solution for Volume Variations in the Residual Limb for Individuals with a Transtibial Amputation. *Sensors* 2024, 24, 4744. <https://doi.org/10.3390/s24144744>

## **Patient Populations**

The Overlay is **suitable for patients at all functional levels K1 to K4 (K-levels).**

1. **New Amputees:** Commonly, newly amputated limbs undergo a reduction in size, shape, and volume at an accelerated rate. The Overlay can be used to help manage these more consistent and rapid volume changes as opposed to having to make up for this loss with numerous sock layers.
2. **Diabetes or Vascular Disease Patients:** Patients with these conditions can experience challenges with the management of prosthetics socks and socket fit. The ease of use of the Overlay can benefit those patients.
3. **Traumatic Amputees:** Traumatic amputations often result in more scar tissue and irregularly shaped residual limbs, making optimal socket fitting more challenging.
4. **Dialysis Patients:** Dialysis patients experience important limb volume fluctuations between and after dialysis treatments.
5. **Cancer Patients:** Patients with amputation due to cancer often return to their pre-diagnosis activity level. However, cancer medications often cause fluctuations in limb volume.
6. **Mature Amputees:** Patients often have atrophied limbs with sensitive areas, making socket fit challenging. The Overlay provides targeted cushioning and expansion to offload pressure from sensitive areas and apply it to pressure-tolerant ones.
7. **Patient that experiences “Bell clapping”** (Distal portion of the socket is loose and the proximal

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portion fits snugly). The Overlay provides targeted cushioning to reposition bony anatomy and accommodate distal limb volume.

### **Sources:**

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