Ethnocare Underlay Reimbursement Guide

For Transtibial Applications

Manufacturer Recommended HCPCS Codes: L8420, L8400

(Transfemoral version planned for release; corresponding above-knee codes L8430 and L8410 noted where applicable)

Product Overview

The **Ethnocare Underlay** is a thin textile sleeve worn directly against the skin, underneath the prosthetic liner, designed to actively manage humidity, sweat, heat, and odor inside the socket throughout the day while the prosthesis is being worn.

Worn **under the liner and within the existing socket**, the Underlay requires no modification to the prosthesis. It works through a **knitted pattern engineered for moisture transportation**, drawing sweat away from the skin and directing it toward a breathable mesh layer where it can evaporate more effectively. With a 0.5 mm layer thickness adding approximately 1 mm of overall thickness, it does not create bulk that would affect socket fit or alignment.

Its textile structure is complemented by two Polygiene technologies: **StayFresh** antimicrobial coating, which inhibits odor-causing bacteria, and **StayCool** thermo-reactive polymer matrix, which is activated by moisture to lower fabric temperature by 2 to 3°C (4.3 to 5.4°F). It serves as an effective, proactive alternative to traditional sweat socks, mid-day doffing, and Botox injections, none of which address the underlying problem of a closed environment that traps moisture, builds heat, and cuts off airflow.

An open and a closed version are available. The open version allows the distal end of the liner to remain in direct contact with the skin, helping maintain suspension while allowing airflow at the proximal opening. The closed version offers the same moisture-management and antimicrobial benefits with a sealed distal end, and can be preferred for patients with more bulbous limb shapes.

Model Information

Version	Model Number Format	Example
Transtibial, Open	UDTT-XX-YY *(XX = size number; YY = length)*	UDTT-28-MD
Transtibial, Closed	UDTT-XX-YY-C *(XX = size; YY = length; C = closed)*	UDTT-28-SH-C

Sizes available: 23, 28, 35. Lengths: Short, Medium, Long, and Extra-Long for the open version; Short and Long for the closed version. Sold each.

Intended Use

The Ethnocare Underlay provides **active moisture, heat, and odor management** for individuals experiencing sweat accumulation, heat buildup, or moisture-related skin and suspension problems inside the prosthetic socket. It is suitable for patients across functional levels K1 to K4 and is compatible with most existing liners and socket systems. The Underlay requires a prosthetic liner to function and should not be used over open wounds or injuries on the residual limb.

Key Indications:

- **Hyperhidrosis:** The patient experiences excessive sweating in the residual limb that interferes with daily prosthetic use. Trapped perspiration inside the liner compromises comfort, skin integrity, and the ability to wear the prosthesis for a full day. Between 34 and 74% of amputees report skin problems and up to 66% experience hyperhidrosis that interferes with daily life.
- **Recurrent Skin Breakdown and Maceration:** Prolonged moisture against the skin softens the tissue and makes it significantly more vulnerable to friction and shear during gait, leading to repeated irritation, maceration, blistering, or breakdown, particularly over high-pressure areas such as the distal tibia, fibular head, adductor region, or ischial tuberosity, where tissue tolerance is already limited.
- **Moisture-Driven Suspension Loss:** Sweat accumulating between the skin and the liner acts as a lubricant, creating micro-movement, pistoning, and rotation inside the socket. This undermines suspension, reduces the patient's confidence in the device, and increases the risk of trips and falls.
- **Heat Buildup Limiting Wear Time:** The sealed socket environment traps metabolic heat, and the patient experiences heat intolerance that limits how long the prosthesis can be worn comfortably. This is compounded during warm weather and physical activity.
- **Folliculitis, Odor, and Dermatological Complications:** Persistent humidity prevents the skin from drying between activity cycles, promoting bacterial proliferation, chronic odor, and dermatological conditions such as folliculitis.

- **Repeated Mid-Day Doffing:** The patient is forced to remove the prosthesis multiple times per day to dry the residual limb and empty accumulated sweat from the liner. This disrupts daily activities, causes additional skin irritation, results in inconsistent suspension on re-donning, and increases the risk of contamination when the device is removed in public or non-sterile environments.
- **Failure of Traditional Moisture-Management Methods:** The patient has been unable to effectively manage socket moisture using traditional methods such as standard sweat socks, which absorb moisture but retain it against the skin, add bulk, lose shape when wet, bunch inside a fitted socket, and retain heat.
- **High Metabolic Heat and Activity Demands:** The patient is highly active and generates elevated metabolic heat and perspiration. Amputees expend between 10 and 40% more energy while walking for transtibial patients, and between 60 and 100% more for transfemoral patients, compared to non-amputees, generating more heat within the socket.
- **Fragile or Vulnerable Skin:** The patient has fragile skin due to diabetes, vascular disease, scar tissue, thin tissue, advanced age, or treatment effects, making the skin more sensitive to friction and humidity and more likely to progress quickly from moisture buildup to breakdown.

Clinical Benefits

1. Reduces Perceived Humidity Inside the Liner

In an Ethnocare case study of 15 lower-limb amputees, users reported a 51% reduction in perceived humidity inside the liner, with average ratings dropping from 8.4 to 4.1 on a 10-point scale. Drier skin is less vulnerable to friction, shear, and breakdown during gait.

2. Reduces Perceived Heat and Improves Thermal Comfort

Users reported a 38% reduction in perceived heat buildup inside the liner, with average ratings dropping from 8.3 to 5.2 on a 10-point scale. By reducing relative humidity at the skin, the Underlay restores evaporative cooling capacity and lowers perceived heat, even without changing the actual temperature.

3. Objectively Lowers Relative Humidity in the Socket

Controlled clinical testing using embedded humidity sensors demonstrated a 17% reduction in objective relative humidity inside the liner, with moisture accumulating at a significantly slower rate during both resting and active phases. This indicates the Underlay begins working immediately, not only during exertion.

4. Protects Skin Integrity and Reduces Breakdown

By keeping the limb-liner interface drier, the Underlay reduces the softening, maceration, and friction that lead to blisters, abrasions, and ulceration over high-pressure areas. This benefit is particularly important for patients with vascular disease, diabetes, thin or fragile skin, or chronic sensitivity.

5. Maintains Suspension by Managing Moisture at the Source

Sweat acting as a lubricant between skin and liner creates pistoning and rotation that undermine suspension. By keeping the skin drier, the Underlay improves liner grip and delivers more consistent, secure suspension throughout the day.

6. Preserves Suspension Without Compromising Fit

The open-ended design allows the distal end of the liner to remain in direct contact with the skin. Traction-force testing confirms that the limb-to-liner contact preserved by this design is sufficient to maintain suspension well beyond the demands of running, so moisture management does not come at the expense of a secure fit.

7. Reduces Odor and Bacterial Growth

Polygiene StayFresh antimicrobial technology, based on silver chloride, inhibits odor-causing bacteria from multiplying, keeping the product and the socket environment fresher through repeated daily use.

8. Reduces the Need for Mid-Day Doffing

By keeping the limb drier throughout the day, the Underlay reduces how often patients must remove the prosthesis to dry the limb or empty sweat from the liner. Several case-study users reported needing to doff their prosthesis mid-day less frequently, supporting uninterrupted activity and more consistent prosthetic use.

9. Integrates Into Nearly Any Existing Setup

The Underlay sits under the liner inside the existing socket with no modification required. It is compatible with pin lock, vacuum (closed model), lanyard, suspension sleeve, and seal-in systems, and with TPE, TPU, silicone, and seal-ring liners, allowing clinicians to introduce it without altering components, suspension methods, or fitting procedures.

HCPCS Coding and Reimbursement

The Underlay aligns with the coding pathway used for under-liner prosthetic sheaths and socks. Based on its function and classification, the manufacturer-recommended L-codes are as follows. Unlike a dedicated volume-management code, these are existing codes used for comparable under-liner products, so coverage policy, allowable amounts, and quantity limits are determined by each payer. Final code selection depends on the patient's configuration and payer requirements, and should be confirmed against local guidelines.

Manufacturer Recommended HCPCS Codes

Code	Long Description	Application
L8400	Prosthetic sheath, below knee, each	Transtibial
L8410	Prosthetic sheath, above knee, each	Transfemoral
L8420	Prosthetic sock, multiple ply, below knee, each	Transtibial
L8430	Prosthetic sock, multiple ply, above knee, each	Transfemoral

Note: L8400 and L8420 are the manufacturer-recommended codes for the currently available transtibial Underlay. L8410 and L8430 apply to the transfemoral version, which is planned for release. The prosthetic sock codes (L8420, L8430) are used for comparable under-liner products such as the Knit-Rite Liner-Liner.

Allowable Status

Because the Underlay is billed under existing sheath and sock codes rather than a dedicated code, there is no single published allowable specific to the device. Allowable amounts for L8400, L8410, L8420, and L8430 are established by each payer and fee schedule. Confirm the applicable allowable with the payer before dispensing.

Quantity and Replacement

The Underlay is designed for daily use and daily cleaning, and can only be worn when completely dry. Quantity allowances and replacement intervals for the applicable sheath and sock codes are set by each payer. Confirm the payer's quantity limits and replacement schedule, and document the patient's wear and hygiene needs to support the quantity dispensed. See Care and Maintenance below for the cleaning requirements that inform wear-time and hygiene planning.

Care and Maintenance

The Underlay is machine washable and practical for daily use. Wash it after each use in warm water below 40°C (104°F), using a mild, pH-balanced detergent free of fragrance, bleach, and dye, then air dry it.

From the Instructions for Use:

- Clean the device after each use only with approved cleansing products, including neutral soap or mild detergent that is pH balanced and free of fragrance, bleach, and dye.
- Clean the device in warm water below 40°C (104°F). Do not wring out the device, to avoid damage.
- Rinse the device thoroughly with clean warm water to remove all soap residues.
- Insert a towel into the device and air dry. Avoid harsh detergents, ironing, and dry cleaning, as any of these can damage the coatings and void the warranty.
- The device can be used only when it is completely dry.

The coatings are engineered to maintain performance through at least 20 wash cycles, after which performance is expected to gradually decline with continued washing. Full care instructions are in the Instructions for Use.

Billing Guidance

Billing Tips:

- Confirm the applicable HCPCS code (L8400/L8420 for transtibial; L8410/L8430 for transfemoral) is on the payer's fee schedule and that an allowable is established.
- Verify the payer's quantity limits and replacement interval for the sheath or sock code being billed.
- **Advance Beneficiary Notice (ABN):** Obtain when coverage is not expected.

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."

Clinical Documentation Guidance

Refer to the complete Medical Necessity Justification Letter example for the Underlay. Adapt as appropriate for your patient's specific situation:

- The patient experiences **excessive sweating or hyperhidrosis** in the residual limb that interferes with daily prosthetic use.
- The patient has **recurrent skin irritation, maceration, or breakdown** linked to trapped moisture inside the liner.
- **Moisture-driven slippage** creates pistoning, rotation, or unreliable suspension inside the socket.
- The patient experiences **heat buildup that limits wear time**, compounded by warm weather or physical activity.
- The patient has **chronic odor or dermatological issues such as folliculitis** from persistent socket humidity.
- The patient is **forced to doff the prosthesis multiple times per day** to dry the limb or empty sweat from the liner.
- Traditional methods such as **sweat socks or Botox injections** are ineffective, impractical, or have failed.
- The patient has **fragile or vulnerable skin** (diabetes, vascular disease, scar tissue, thin tissue, advanced age, or treatment effects).
- The patient is **highly active (K3 to K4)** and generates elevated metabolic heat and perspiration.

Physician Documentation Checklist

- States the medical need for a **dedicated moisture- and heat-management interface** beyond traditional sweat socks.
- Documents the **expected medical benefit** the patient will receive from active moisture and heat management (for example, reduced skin breakdown, improved wear time, or more reliable suspension).
- **Prescribes** the moisture-management interface.

Prosthetist Documentation Checklist

- General and amputation information.
- Medical history. If the patient experiences hyperhidrosis, recurrent skin breakdown, or moisture-related complications due to a medical condition, document that fact.
- Daily life: physical environment, support people, activities, and challenges. Document how sweat and heat affect this patient, and whether the patient navigates environments where they cannot remove the prosthesis to dry the limb.
- Patient goals for prosthetic service.
- Prosthetic history.
- Examination of existing prosthesis.
- Physical evaluation: gait, residuum, measurements, outcome measures.
- Assessment and rationale:
    - Why was the Underlay chosen?
    - What alternatives were considered and why were they inadequate?
    - How does it address the patient's medical necessity?
    - Care and maintenance requirements.

Potential Indications for Coverage

- Excessive sweating or hyperhidrosis affecting prosthetic use
- Recurrent moisture-related skin irritation, maceration, or breakdown
- Heat buildup limiting prosthetic wear time
- Moisture-driven suspension instability
- Chronic odor or dermatological complications from socket humidity

Prior Authorization

- Ensure the applicable code is on the payer fee schedule and learn whether the payer has established its own allowable.
- Confirm whether the payer requires prior authorization for prosthetic sheaths or socks, and what documentation is needed.

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: Underlay TT (open or closed)

Contact Ethnocare Reimbursement Support

For assistance with coding, documentation, or payer communication:

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