

# SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE WORK

## Skin Substitutes for Chronic Skin Ulcers

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<b>Population description</b>	Individuals with chronic skin ulcers <i><b>Population scoping notes: Considered limiting scope to diabetic foot ulcers and venous leg ulcers, sacral decubitus ulcers, but decided on the broader definition above</b></i>
<b>Intervention(s)</b>	Skin substitutes (e.g., Apligraf®, Dermagraft®, OrCel®, EpiFix®, Grafix®, TheraSkin®) . Stratify by category (not brand)  <i><b>Intervention exclusions:</b> Product not available in the U.S.</i>
<b>Comparator(s)</b>	Usual care (e.g., skin grafts, compression therapy, specialized dressings, debridement, pressure relieving devices), other wound healing products (e.g., wet-to-dry dressing changes, DuoDERM®, Betadine®, sucrose), Wound Vac, Hyperbaric Oxygen, topical oxygen.
<b>Outcome(s) (up to five)</b>	<i><b>Critical:</b> Deep soft tissue or bone infections, complete wound healing, ulcer recurrence</i> <i><b>Important:</b> Time to complete wound healing, , adverse effects</i> <i><b>Considered but not selected:</b> Quality of life, cellulitis, sepsis, death, need for surgical management.</i>
<b>Key coverage questions/theory of change for this report</b>	<ol style="list-style-type: none"> <li>1. What is comparative effectiveness of different types of skin substitutes compared with wound care alternatives for individuals with chronic skin ulcers? Include consideration of:                         <ol style="list-style-type: none"> <li>a. Age</li> <li>b. Body mass index (BMI)</li> <li>c. Comorbidities</li> <li>d. Site of ulcer</li> <li>e. Ulcer etiology (e.g. infectious, pressure or circulatory)</li> <li>f. Wound severity</li> <li>g. Prior need for skin substitute</li> <li>h. Failure of prior therapies</li> </ol> </li> <li>2. What adverse events are associated with biosynthetic skin substitutes?</li> </ol>