



Medical Coverage Policy

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Pressure Reducing Surfaces

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The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses pressure reducing support surfaces.

Coverage Policy

Coverage for pressure reducing support surfaces varies across plans. Refer to the customer's benefit plan document for coverage details.

Pressure reducing surfaces are not considered mattresses. For information on the use of mattresses refer to the Cigna Medical Coverage Policy Hospital Beds and Accessories.

If coverage for the specific pressure reducing support surface requested is available, the following conditions of coverage apply.

Pressure reducing support surfaces are considered medically necessary when the following criteria are met:

- **A Group 1 pressure reducing support surface** (HCPCS codes E0181, E0182, E0184, E0185, E0186, E0187, E0196, E0197, E0198, E0199, and A4640) is considered medically necessary when the

individual has prodromal skin changes consistent with the development of a pressure ulcer **OR** cannot independently make changes in body position significant enough to alleviate pressure **AND** is at risk for developing a pressure ulcer **AND ANY** of the following criteria is met:

- fecal or urinary incontinence
 - altered sensory perception
 - compromised circulatory status
- **A Group 2 pressure reducing support surface** (HCPCS codes E0193, E0277, E0371, E0372, and E0373) is considered medically necessary when **ANY** of the following criteria is met:
 - Large or multiple Stage 3 or 4 pressure ulcers are present on the trunk or pelvis.
 - A myocutaneous flap or skin graft has been performed within the past 60 days for a pressure ulcer on the trunk or pelvis **AND** the individual has been on a Group 2 or 3 support surface immediately prior to a recent discharge from a hospital or nursing facility (discharge within the past 30 days). Following myocutaneous flap or skin graft, coverage is usually limited to 60 days from the date of surgery.
 - Multiple Stage 2 pressure ulcers are located on the trunk or pelvis and have not improved over the past month despite the use of an appropriate Group 1 support surface **AND** a comprehensive ulcer treatment program that includes:
 - education of the individual and caregiver on the prevention and/or management of pressure ulcers
 - regular assessment by a nurse, physician or other licensed health care practitioner (i.e., usually at least weekly for an individual with a Stage 3 or 4 ulcer)
 - appropriate turning and positioning
 - appropriate wound care for a Stage 2, 3 or 4 ulcer
 - appropriate management of moisture/incontinence
 - nutritional assessment and intervention consistent with the overall plan of care
- **A Group 3 pressure reducing support surface** (HCPCS code E0194) is considered medically necessary when **ALL** of the following criteria are met:
 - The individual has a Stage 3 or Stage 4 pressure ulcer.
 - The individual is bedridden or chair-bound as a result of severely limited mobility.
 - Without an air-fluidized bed, the individual would require institutionalization.
 - The air-fluidized bed is ordered following a comprehensive assessment and evaluation of the individual after at least 30 days indicating that all of the following conservative medical management has been attempted without success:
 - education of the individual and caregiver on the prevention and/or management of pressure ulcers
 - assessment by a physician, nurse or other licensed health care practitioner at least weekly
 - appropriate turning and positioning
 - use of a Group 2 support surface, if appropriate
 - appropriate wound care
 - appropriate management of moisture/incontinence
 - nutritional assessment and intervention consistent with the overall plan of care
 - None of the following contraindications to the use of an air-fluidized bed pertain:
 - There is severe coexisting pulmonary disease (lack of firm back support makes coughing ineffective, and dry air inhalation thickens pulmonary secretions).
 - Treatment is required that utilizes wet soaks or moist dressings that are not protected by an impervious covering, such as plastic wrap or other occlusive material.
 - The caregiver is unwilling or unable to provide the type of care required for an individual on an air-fluidized bed.
 - The structural support is inadequate to sustain the weight of an air-fluidized system, which generally weighs at least 1600 pounds.
 - The existing electrical system cannot adequately support the anticipated increase in energy consumption.

General Background

This information on pressure reducing surfaces has been developed through consideration of medical necessity and generally accepted standards of medical practice, as well as review of medical literature and government approval status.

In 2016, the National Pressure Ulcer Advisory Panel (NPUAP) redefined the definition: pressure injury replaces the terms “pressure ulcer,” “decubitus ulcer,” and “bed sores.” The NPUAP defines pressure injury as a localized area of damage to the skin and/or underlying soft tissue over a bony prominence as a result of pressure or pressure in combination with shear. Skin can be intact or have an open ulcer. Treatment is based on the stage and characteristics of the pressure injury. Pressure relief and nutrition are important interventions. Host-specific factors such as immobility, sensory loss, incontinence, reduced perfusion, and compromised nutritional status culminates in tissue damage which have profound effects on the healing process and have a greater influence than what is put on the wound. The cornerstone of therapy involves the use of appropriate wound dressings, pressure-reducing devices, treatment of infection, debridement, and surgical consultation when appropriate (Welesko and Javier, 2019; Wester, 2019).

Initial treatment for pressure injuries is to relieve pressure by positioning the patient frequently and at a fixed interval to relieve pressure over the compromised area. A number of medical devices are designed to relieve pressure. The choice of devices should be based on durability, ease of use, and patient comfort. These devices can be classified as static or dynamic. Static devices include air-, gel-, or water-filled containers that reduce the tissue–surface interface. Dynamic devices use a power source to inflate compartments that support the patient’s weight or alternate the pressure on different areas of the body. A static device is recommended when the patient has good bed mobility. A dynamic device is recommended when the patient cannot self-position in bed. A check for bottoming out is generally done for all devices. To check for bottoming out, the hand is inserted palm upward under the patient’s sacrum between the device and the bed surface. It is recommended that if no air column is apparent between the patient and the bed surface, the device is ineffective and should be changed. Also, it is suggested that patients who fail to improve, or who have multiple pressure injuries, should be considered for a dynamic-type device, such as a low-air-loss bed or air-fluidized bed (Welesko and Javier, 2019; Wester, 2019).

Staging of Pressure Ulcers

When evaluating pressure ulcers, a staging system is typically used that measures tissue destruction by classifying wounds according to the tissue layers involved. In 2016, the National Pressure Ulcer Advisory Panel (NPUAP) renamed the term pressure ulcer with pressure injury and redefined the definition of a pressure ulcer and the stages of pressure injury including the original four stages and updating two stages on deep tissue injury and unstageable pressure injury. In addition to the change in terminology, Arabic numbers replace Roman numerals to identify the stages. Two additional pressure injury definitions: Medical device and Mucosal Membrane Pressure Injury were added.

The updated staging system includes the following definitions:

Pressure Injury:

A pressure injury is localized damage to the skin and underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue.

Stage 1 Pressure Injury: Non-blanchable erythema of intact skin

Intact skin with a localized area of non-blanchable erythema, which may appear differently in darkly pigmented skin. Presence of blanchable erythema or changes in sensation, temperature, or firmness may precede visual changes. Color changes do not include purple or maroon discoloration; these may indicate deep tissue pressure injury.

Stage 2 Pressure Injury: Partial-thickness skin loss with exposed dermis

Partial-thickness loss of skin with exposed dermis. The wound bed is viable, pink or red, moist, and may also present as an intact or ruptured serum-filled blister. Adipose (fat) is not visible and deeper tissues are not visible. Granulation tissue, slough and eschar are not present. These injuries commonly result from adverse microclimate and shear in the skin over the pelvis and shear in the heel. This stage should not be used to describe moisture associated skin damage (MASD) including incontinence associated dermatitis (IAD), intertriginous dermatitis (ITD), medical adhesive related skin injury (MARS), or traumatic wounds (skin tears, burns, abrasions).

Stage 3 Pressure Injury: Full-thickness skin loss

Full-thickness loss of skin, in which adipose (fat) is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.

Stage 4 Pressure Injury: Full-thickness skin and tissue loss

Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible. Epibole (rolled edges), undermining and/or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.

Unstageable Pressure Injury: Obscured full-thickness skin and tissue loss

Full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable eschar (i.e. dry, adherent, intact without erythema or fluctuance) on the heel or ischemic limb should not be softened or removed.

Deep Tissue Pressure Injury: Persistent non-blanchable deep red, maroon or purple discoloration

Intact or non-intact skin with localized area of persistent non-blanchable deep red, maroon, purple discoloration or epidermal separation revealing a dark wound bed or blood filled blister. Pain and temperature change often precede skin color changes. Discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury, or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle or other underlying structures are visible, this indicates a full thickness pressure injury (Unstageable, Stage 3 or Stage 4). Do not use DTPI to describe vascular, traumatic, neuropathic, or dermatologic conditions.

Additional pressure injury definitions:

Medical Device Related Pressure Injury: This describes an etiology. Medical device related pressure injuries result from the use of devices designed and applied for diagnostic or therapeutic purposes. The resultant pressure injury generally conforms to the pattern or shape of the device. The injury should be staged using the staging system.

Mucosal Membrane Pressure Injury: Mucosal membrane pressure injury is found on mucous membranes with a history of a medical device in use at the location of the injury. Due to the anatomy of the tissue these injuries cannot be staged.

Group 1 Pressure Reducing Support Surfaces: These include HCPCS codes that stand for static overlays and mattress replacements:

- **Pressure Pads for Mattresses:** Code E0185 and codes E0197-E0199, termed pressure pad for mattress, represent nonpowered pressure reducing mattress overlays. These devices are designed to be placed on top of standard hospital or home mattresses.
 - A gel mattress overlay (E0185) is a gel layer with a height of two or more inches.

- An air mattress overlay (E0197) is characterized by interconnected air cells that have a cell height of three or more inches and are inflated with an air pump.
- A water mattress overlay (E0198) is characterized by a filled height of three or more inches.
- A foam mattress overlay (E0199) possesses the following characteristics:
 - base thickness of two or more inches and either of the following:
 - peak height of three or more inches if the overlay is convoluted (e.g., egg crate)
 - overall height of at least three inches if the overlay is not convoluted
 - foam of such density and other qualities that it provides adequate pressure reduction
 - durable waterproof cover
- **Nonpowered Pressure Reducing Mattresses**
 - An air, water or gel mattress (E0186, E0187, E0196) has the following characteristics:
 - height of five or more inches of the air, water or gel layer
 - durable, waterproof cover
 - can be placed directly on a hospital bed frame
 - A foam mattress (E0184) has the following characteristics:
 - height of five or more inches
 - foam of such density and other qualities that it provides adequate pressure reduction
 - durable waterproof cover
 - can be directly placed on a hospital bed frame
- **Powered Pressure Reducing Mattress Overlay Systems:** Codes E0181, E0182, and A4640 represent powered pressure reducing mattress overlay systems (alternating pressure or low air loss) that have the following characteristics:
 - An air pump or blower provides either sequential inflation and deflation of air cells or low interface pressure throughout the overlay.
 - The inflated cell height of the air cells through which air circulates is two and one-half inches or more.
 - The height of the air chambers, proximity of the air chambers to one another, frequency of air cycling (for alternating pressure overlays), and air pressure provide adequate patient lift, reduce pressure and prevent bottoming out.

Group 2 Pressure Reducing Support Surfaces: These include HCPCS codes that are defined as follows:

- **Powered Pressure Reducing Mattress:** Code E0277 stands for a powered pressure reducing mattress (alternating pressure, low air loss, or powered flotation without low air loss) that has the following characteristics:
 - An air pump or blower provides either sequential inflation and deflation of the air cells or low interface pressure throughout the mattress.
 - The inflated cell height of the air cells through which air circulates is five inches or more.
 - The height of the air chambers, proximity of the air chambers to one another, frequency of air cycling (for alternating pressure mattresses), and air pressure provide adequate patient lift, reduce pressure and prevent bottoming out.
 - The surface is designed to reduce friction and shear.
 - The surface can be placed directly on a hospital bed frame.
- Code E0193 describes a semi-electric or total electric hospital bed with a fully integrated powered pressure reducing mattress which has all the characteristics defined above.
- **Advanced Nonpowered Pressure Reducing Mattress Overlay:** Code E0371 describes an advanced, nonpowered pressure reducing mattress overlay with the following characteristics:
 - The height and design of individual cells provide significantly more pressure reduction than in a group 1 overlay and prevent bottoming out.
 - The total height is three inches or more.
 - The surface is designed to reduce friction and shear.

- There is documented evidence to substantiate that the product is effective in treating conditions described by the coverage criteria for group 2 support surfaces.
- **Powered Pressure Reducing Mattress Overlay:** Code E0372 describes a powered pressure reducing mattress overlay (low air loss, powered flotation without low air loss, or alternating pressure) with the following characteristics:
 - An air pump or blower provides either sequential inflation and deflation of the air cells or low interface pressure throughout the overlay. The inflated cell height of the air cells through which air circulates is 3.5 inches or more.
 - The height of the air chambers, proximity of the air chambers to one another, frequency of air cycling (for alternating pressure overlays), and air pressure provide adequate patient lift, reduce pressure and prevent bottoming out.
 - The surface is designed to reduce friction and shear.
- **Advanced Nonpowered Pressure Reducing Mattress:** Code E0373 describes an advanced, manually powered pressure reducing mattress with the following characteristics:
 - The height and design of individual cells provide significantly more pressure reduction than those in a group 1 mattress and prevent bottoming out.
 - The total height is five inches or more.
 - The surface is designed to reduce friction and shear.
 - There is documented evidence to substantiate that the product is effective in treating conditions described by the coverage criteria for group 2 support surfaces.
 - The mattress can be placed directly on a hospital bed frame.

Group 3 Pressure Reducing Support Surfaces are described by a single HCPCS code, defined as follows:

- **Air-Fluidized Bed:** Code E0194 describes an air-fluidized bed, a device with **ALL** of the following characteristics:
 - The bed employs circulation of filtered air through silicone-coated ceramic beads, creating the characteristics of fluid.
 - The bed consists of a tank filled with silicone-coated microsphere beads that resemble grains of sand.
 - The tank is covered with a loose-fitting filter sheet that separates the patient from the beads.
 - Room air is drawn into the base unit, then filtered, heated and pushed into the tank through a diffuser board.
 - The airflow suspends the beads, causing them to take on properties of a fluid.
 - The sheet moves freely above the patient through the fluid. Usually, the patient sinks only 4–6 inches into the beads, and the pressure put on the skin is well below capillary closing pressure.
 - The sheet is permeable to the downward flow of body fluids (e.g., wound drainage, urine, perspiration). As body fluids come in contact with the beads, the beads clump and drop to the bottom of the tank, where the alkaline environment kills the bacteria. The clumps are removed during routine maintenance.
 - Patient transfers in and out of bed may be difficult and, in most models, the head cannot be elevated.
 - When the airflow is turned off, the beads settle into a mold around the body, creating a support surface that stabilizes the patient for nursing care, wound cleaning and other care needs.

Literature Review

In a multi-center, randomized controlled trial, Nixon et al. (2006b) tried to determine whether there are differences between alternating pressure overlays and alternating pressure mattresses in the development of new pressure ulcers, healing of existing pressure ulcers, and patient acceptability. Participants (n=1972) were randomized to an alternating pressure mattress (n=982) or an alternating pressure overlay (n=990). The outcome measure was the proportion of participants developing a new pressure ulcer of grade 2 (i.e., partial thickness wound involving epidermis/dermis only) or worse; time to development of new pressure ulcers; proportion of participants developing a new ulcer within 30 days; healing of existing pressure ulcers; and patient acceptability. The patients were at least 55 years of age, admitted to vascular, orthopedic, medical, or care of

elderly people wards, either as acute or elective admissions, in the previous 24 hours. Other eligibility criteria included an expected length of stay of at least seven days and either limitation of activity and mobility or an existing pressure ulcer of grade 2. Intention to treat analysis found no difference in the proportion of participants developing a new pressure ulcer of grade 2 or worse (10.7% overlay patients, 10.3% mattress patients; difference 0.4%, 95% confidence interval—2.3%–3.1%, $p=0.75$). More overlay patients requested change to a mattress owing to dissatisfaction (23.3%) than mattress patients (18.9%, $p=0.02$).

In a multi-center retrospective study, Ochs et al. (2005) compared pressure ulcer healing rates between different support surfaces. Data was analyzed from eligible nursing home residents ($n=664$) enrolled in the National Pressure Ulcer Long-Term Care Study. Support surfaces were categorized as Group 1 (i.e., static overlays and replacement mattresses), Group 2 (i.e., low air loss beds, alternating pressure, and powered/nonpowered overlays/mattresses) and Group 3 (i.e., air-fluidized beds). Pressure ulcer healing rates were greatest for Stage III/IV ulcers on Group 3 surfaces versus Group 1 or 2 surfaces. Residents on Group 1 and Group 3 surfaces had fewer hospitalizations and emergency room visits than those on Group 2 surfaces despite significantly greater illness in residents on Group 2 and 3 versus Group 1 surfaces.

In a systematic review, Reddy et al. (2006) studied various interventions to prevent pressure ulcers. Fifty-nine randomized controlled trials (RCTs) were selected. Interventions in the studies were grouped into three categories (i.e., addressing impairments in mobility, nutrition, or skin health). Strategies that addressed impaired mobility included the use of support surfaces, mattress overlays on operating tables, and specialized foam and sheepskin overlays. The authors concluded that “given the current evidence, using support surfaces, repositioning the patient, optimizing nutrition status, and moisturizing sacral skin are appropriate strategies to prevent pressure ulcers. Although a number of RCTs have evaluated preventive strategies for pressure ulcers, many of them had important methodological limitations. There is a need for well-designed RCTs that follow standard criteria for reporting nonpharmacological interventions.”

An updated Cochrane review by McInnes et al. (2018) assessed the effectiveness of support services for the treatment of pressure ulcers. A total of 19 trials involving 3241 participants met the inclusion criteria. Most trials were small, with sample sizes ranging from 20 to 1971, and were generally at high or unclear risk of bias. The authors summarized that overall the evidence is of low to very low certainty and was primarily downgraded due to risk of bias and imprecision with some indirectness. Based on the current evidence, it is unclear whether any particular type of low- or high-tech support surface is more effective at healing pressure ulcers than standard support surfaces. concluded that “There is no conclusive evidence about the superiority of any support surface for the treatment of existing pressure ulcers. Methodological issues included variations in outcomes measured, sample sizes and comparison groups. Many studies had small sample sizes and often there was inadequate description of the intervention, standard care and co-interventions. Individual study results were often inadequately reported, with failure to report variance data common, thus hindering the calculation of mean differences. Some studies did not report P values when reporting on differences in outcomes. In addition, the age of some trials (some being 20 years old), means that other technologies may have superseded those investigated. Further and rigorous studies are required to address these concerns and to improve the evidence base before firm conclusions can be drawn about the most effective support surfaces to treat pressure ulcers”.

Centers for Medicare & Medicaid Services (CMS):

- National Coverage Determinations (NCDs): National Coverage Decision (NCD) for Air-Fluidized Bed (280.8). Effective November 1, 2000. The Coverage Policy is broader in scope than the NCD. Refer to the CMS NCD table of contents link in the reference section.
- Local Coverage Determinations (LCDs): Multiple LCDs found. Refer to the LCD table of contents link in the reference section.

Use Outside of the US

No relevant information.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

The following Group 1, 2 and 3 pressure reducing support devices are considered medically necessary when criteria in the applicable policy statements listed above are met and only when coverage is available for the specific item. Coverage for pressure reducing support surfaces varies across plans. Refer to the customer's benefit plan document for coverage details:

Group 1 Pressure Reducing Support Surface

HCPCS Codes	Description
A4640	Replacement pad for use with medically necessary alternating pressure pad owned by patient
E0181	Powered pressure reducing mattress overlay/pad, alternating, with pump, includes heavy duty
E0182	Pump for alternating pressure pad, for replacement only
E0184	Dry pressure mattress
E0185	Gel or gel-like pressure pad for mattress, standard mattress length and width
E0186	Air pressure mattress
E0187	Water pressure mattress
E0196	Gel pressure mattress
E0197	Air pressure pad for mattress, standard mattress length and width
E0198	Water pressure pad for mattress, standard mattress length and width
E0199	Dry pressure pad for mattress, standard mattress length and width

Group 2 Pressure Reducing Support Surface

HCPCS Codes	Description
E0193	Powered air flotation bed (low air loss therapy)
E0277	Powered pressure-reducing air mattress
E0371	Nonpowered advanced pressure reducing overlay for mattress, standard mattress length and width
E0372	Powered air overlay for mattress, standard mattress length and width
E0373	Nonpowered advanced pressure reducing mattress

Group 3 Pressure Reducing Support Surface

HCPCS Codes	Description
E0194	Air fluidized bed

*Current Procedural Terminology (CPT®) ©2019 American Medical Association: Chicago, IL.

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