Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First	**Submission Date**: 2/1/2025
Policy Number: ccp.1546	**Effective Date:** 1/2025 **Revision Date:** January 1, 2025
Policy Name: Emerg Auto-Emersion Therapy system and Dolphin Fluid Immersion Simulation system for pressure injury	

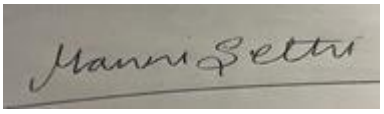
Type of Submission – Check all that apply:

- ☒ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Statewide PDL**

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

New Policy

Name of Authorized Individual (Please type or print):	**Signature of Authorized Individual:**
Manni Sethi, MD, MBA, CHCQM	

Keystone First
Family of Health Plans

Emerg Auto-Emersion Therapy system and Dolphin Fluid Immersion Simulation system for pressure injury

Clinical Policy ID: CCP.1546

Recent review date: 1/2025

Next review date: 5/2026

Policy contains: Dolphin, Emerg, FIS, fluid immersion simulation, pressure support surface, pressure ulcer.

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's clinical policies are not guarantees of payment.

Coverage policy

The Emerg® Auto-Emersion Therapy® system (Ethos Therapy Solutions, Blue Bell, Pennsylvania) and the Joerns® Dolphin Fluid Immersion Simulation® System (Joerns Healthcare, Charlotte, North Carolina) support surfaces are investigational/not clinically proven and, therefore, not medically necessary to prevent or treat pressure injuries.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Non-powered or powered pressure-reducing mattresses and mattress overlays.
- Other immersive support surfaces (e.g., high-specification foam mattresses and air fluidized therapy mattresses).

Background

Pressure injuries, also called pressure ulcers, decubitus ulcers, and bedsores, are localized damage to the skin and underlying soft tissue resulting from prolonged or severe pressure aided by shear and friction forces (Edsberg, 2016). They usually occur over a bony protrusion such as the sacrum, hip, or heel, or may be related to prolonged medical device use. While largely preventable, pressure injuries pose a significant burden to

hospitals and long-term care facilities and result in decreased quality of life and increased morbidity and mortality. In the United States, an estimated one to three million pressure injuries occur annually (Mervis, 2019).

The most common risk factors for developing pressure injuries include immobility, exposure to moisture, reduced perfusion, malnutrition, and sensory loss. Among older patients, skin changes associated with aging can result in decreased resistance to shearing forces, placing them at increased risk for pressure injuries (Mondragon, 2024).

The National Pressure Injury Advisory Panel staging system is widely used to describe pressure injuries (Edsberg, 2016):

- Stage 1: Intact skin with a localized area of nonblanchable erythema, which may appear differently in darkly pigmented skin.
- Stage 2: Partial-thickness loss of skin with exposed dermis.
- Stage 3: Full-thickness skin loss, in which adipose tissue (body fat) is visible in the ulcer and granulation tissue and epibole (rolled wound edges) is often present.
- Stage 4: Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage, or bone in the injury.
- Unstageable: Full-thickness loss of skin tissue that is obscured by eschar or slough.
- Deep tissue: Intact or nonintact skin with localized area of persistent nonblanchable erythema deep red, maroon, purple discoloration, or epidermal separation revealing a dark wound bed or blood-filled blister, which may appear differently in darkly pigmented skin. Pain and temperature changes often precede skin color changes.

General care for preventing the development and worsening of pressure injuries involves a holistic approach consisting of pain control, nutrition optimization, wound care, and pressure redistribution with regular changes in positioning and the use of support surfaces. Support surfaces can alleviate pressure and facilitate blood flow to tissues, thereby preventing skin and soft tissue distortion (Mondragon, 2024).

Therapeutic support surfaces are classified as active or reactive. The main difference between the surfaces is how they redistribute pressure on the body. An active surface, also known as a dynamic surface, mechanically redistributes pressure by sequentially altering the parts of the body that bear load, independent of the applied load. Reactive surfaces, also known as static surfaces, are powered or non-powered support surfaces capable of changing load distribution properties only in response to applied load (National Pressure Injury Advisory Panel, 2019).

Some support surfaces have the ability to immerse or envelop the patient to achieve a fluid state and redistribute pressure over greater body surface area to reduce concentrations of weight over bony prominences. Examples are high-specification foam mattresses (reactive support surfaces) and air fluidized therapy mattresses (active support surfaces). Each offers the ability to manage the heat and humidity (microclimate) of the skin. However, while air fluidized therapy surfaces supply relatively high levels of envelopment and immersion compared to other support surfaces, they are expensive, difficult to maintain and adjust, heavier than a standard bed, and not always suitable for home use (Earlam, 2016).

New immersion therapy options use advanced three-dimensional immersion technology to simulate full immersion and envelopment, automatically adjusting to patient repositioning, to achieve greater transfer of surface pressures and preserve nearly normal tissue perfusion and oxygenation (Ethos Therapy Solutions, 2021; Joerns Healthcare, 2024). Two options are the Emerg® Auto-Emersion Therapy® system (Ethos Therapy Solutions, Blue Bell, Pennsylvania) and the Joerns® Dolphin Fluid Immersion Simulation® System (Joerns Healthcare, Charlotte, North Carolina). The Dolphin System is indicated for the treatment and prevention of all stages of pressure injury, for patients at risk for pressure injury, for the complications of immobility, and for

patients with healing grafts and flap sites. The Dolphin System may be used in the home and is available to fit standard and bariatric hospital beds, tables, wheelchairs, and stretcher pads (Joerns Healthcare, 2024).

Findings

Guidelines

A joint guideline by the European Pressure Ulcer Advisory Panel, the National Pressure Injury Advisory Panel, and the Pan Pacific Pressure Injury Alliance (2019) issued recommendations for the prevention and treatment of pressure injuries. Support surfaces are one aspect of pressure injury prevention that should be used within the holistic patient management framework. The choice of support surface is multifactorial.

Recommendations on support surfaces that offer immersion and envelopment capability are summarized as follows. The guideline does not specify the use of fluid immersion simulation systems and acknowledges the general low-quality nature of the evidence (European Pressure Ulcer Advisory Panel, 2019):

- For patients who are susceptible to pressure injuries, a high-specification foam mattress or overlay or a reactive air mattress or overlay may be considered. Overall, the relative effectiveness of reactive air mattresses in comparison to standard foam mattresses, or the comparative effectiveness of different types of reactive mattresses in preventing pressure injuries, is conflicting and inconclusive.
- For patients with existing pressure injuries, a specialty support surface should be considered when: the patient cannot be positioned off the pressure injury; has pressure injuries on two or more turning surfaces that limit repositioning options; has a pressure injury that either fails to heal or deteriorates despite appropriate comprehensive care; is at high risk for additional pressure injuries; has undergone myocutaneous flap or graft surgery; is uncomfortable; or “bottoms out”’ on the current support surface. Specialty support surfaces to consider include alternating pressure air mattresses, mattresses with a low-air-loss feature, and air fluidized beds. However, the available evidence for these support surfaces is limited and conflicting.
- For patients with Category/Stage III or IV pressure injuries, providers should assess the relative benefits of using an air fluidized bed to facilitate healing while reducing skin temperature and excess hydration.

In patients who are at an increased risk of developing a pressure injury, the American College of Physicians issued recommendations for using advanced static mattresses (foam or gel) or advanced static overlays (e.g., sheepskin or a pad filled with air, water, gel, or foam), and against using alternating-air mattresses or alternating-air overlays (Qaseem, 2015).

The Wound, Ostomy, and Continence Nurses Society (undated) developed an online evidence-based and consensus-based algorithm to aid in choosing the appropriate support surface. Contraindications to using reactive surfaces with constant low pressure, air-fluidized, or low air loss features include an unstable cervical, thoracic, or lumbar spine; cervical or skeletal traction; weight limitations, and Trendelenburg positioning. Support surfaces using a fluid immersion simulation system were not listed as a separate feature with specific recommendations, but the Dolphin system was listed in their product formulary.

Evidence review

For the prevention and management of pressure injury, several Cochrane reviews have examined the relative effectiveness of therapeutic pressure support surfaces. Support surfaces offering immersion therapy options were addressed, but none of the reviews included studies of fluid immersion simulation systems. Shi (2021) summarized the evidence from those reviews. Most of the available evidence on support surfaces was published more than 20 years ago and is not inclusive of contemporary support surfaces. The evidence is of low quality, and the superiority of any support surface for preventing or treating pressure injuries cannot be determined.

The evidence suggests static or alternating pressure air mattresses or overlays, and gel pads used on operating tables may be more effective than foam mattresses for preventing pressure injuries. Static air mattresses or overlays may be better than foam mattresses for healing pressure injuries, but at a higher cost. High-quality experimental studies comparing support surfaces are lacking. The effects of the site and stage of the pressure injuries on healing outcomes, patient comfort, and quality of life have not been adequately studied (Shi, 2021).

The evidence for fluid immersion simulation systems consists of one small, manufacturer-sponsored trial examining the relative effectiveness of the Dolphin system and air-fluidized beds on surgical flap closure outcomes. We found no studies examining its use for the treatment and prevention of all stages of pressure injury or for the complications of mobility, and we found no studies of other fluid immersion simulation therapy products.

The randomized controlled trial enrolled adults with stage 3 or 4 pressure injuries, two or fewer pressure injuries, and a history of less than three surgical closures. They were randomized to either the Dolphin group (n = 38) or the air-fluidized bed group (n = 42). At two weeks after surgery, the flap failure rate was similar between groups (14% vs. 12%; *P* = .84), as were nurse acceptance and patient acceptance rates. The flap failure rates between groups remained similar at one-year follow-up. The Dolphin group experienced a higher complication rate, notably dehiscence and maceration (40% vs. 17%; *P* = .0296), but after the addition of a microclimate regulation device, the flap failure rate (71% vs. 16%; *P* = .001) and complication rate (33% vs. 0%; *P* = .011) decreased significantly (Joshi, 2022).

References

On October 31, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "beds" (MeSH), "pressure ulcer/prevention and control" (MeSH), "immersion therapy," and "fluid immersion simulation." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

1/2025: initial review date and clinical policy effective date: 2/2025