Pressure Ulcer Whitepaper:
EZTREK™ Medical Food Accelerates Healing and Prevents Recurrence Reducing Costs and Exposure to Fines & Litigation

Pressure ulcers continue to be a common health problem in long-term care:[1]

> "Pressure ulcers have become so common in long-term care that federal regulations now articulate pressure ulcer standards or guidelines of care and prevention.
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> "Although the cost of pressure ulcer prevention remains elusive, costs associated with their treatment have been conservatively estimated to range from $500 to $50,000 per ulcer. These costs do not account for the pain and suffering commonly associated…."
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> "Given the impending capitated system and the increasing litigious nature in long-term care, preventing pressure ulcers is essential."

Pressure ulcers are high-cost adverse events across the spectrum of health care settings. 2.5 million patients will develop a pressure ulcer.[2] These ulcers typically result from prolonged periods of uninterrupted pressure on the skin, soft tissue, muscle, or bone.[3] Diabetes is associated with an increased risk or wound complications and readmission in patients with surgically managed pressure ulcers.[4]

Pressure ulcers are a significant issue in long-term care hospitals (LTCHs) / continuing (long-term) care retirement communities including assisted daily living accommodations (ADL), in-patient rehabilitation facilities (INFs) and skilled nursing facilities (SNFs). If the patient does not have a PU on admittance, Medicare / insurance will likely not pay for treatment.

Trials makes clear:[5]

> "Patients with pressure ulcers (PUs) are at high risk for further complications, such as nosocomial infections [acquired in a healthcare facility] and sepsis, and they experience longer lengths of hospital stay.
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> "PUs represent a significant financial burden to healthcare organizations.
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> "Nursing homes have high incidences of pressure ulcer. In a hospital setting it is difficult to completely heal hospital-acquired pressure ulcers in a short period of time. Even if completely healed, the recurrence is high. Patients sustaining falls have a significantly

[1] Lyder, C., et al., "A comprehensive program to prevent pressure ulcers in long-term care: exploring costs and outcomes," *Ostomy Wound Manage*, 2002 Apr;48(4):52-62.
[2] "Preventing pressure ulcers in hospitals," Agency for healthcare research and quality (AHRQ), October 2014.
[3] RTI international, Skilled nursing facility quality reporting program — specifications for percent of residents or patients with pressure ulcers that are new or worsened (NQF #0768), August 2016.
[4] Alfonso, A., et al., "Diabetes is associated with an increased risk or wound complications and readmission in patients with surgically managed pressure ulcers," *Wound repair and regeneration*, 27 (3) May/June 2019: 249-256.
[5] Lechner, A., et al., "Outcomes for pressure ulcer trials (OUTYPUTS): protocol for the development of a core domain set for trials evaluating the clinical efficacy or effectiveness of pressure ulcer prevention interventions," *Trials*, (2019) Jul 22;20(1):449.

increased risk to develop HAPUs (18Xs higher). **Low oxygen saturation levels were significantly associated** with increased HAPUs."

"Therapy for advanced stages of pressure ulcers is expensive and prolonged."[6]

Ischemia is recognized as one of the most important contributors to ulcer formation, triggering a sterile inflammatory cascade that culminates in necrosis of native skin cells and ulceration.[7] Diabetic patients are at increased risk.

Care Facilities

Patients of long-term care facilities are at risk:[1]

"The US Center for Medicare and Medicaid services included pressure ulcers as one of the three sentinel events for long-term care; therefore, the formation of a pressure ulcer or subsequent deterioration of a pressure ulcer can lead to significant monetary penalties (maximum $10,000/day) in long-term care.

"…This model revealed that the most expensive component of pressure ulcer prevention was the labor cost of $277.15 per month (licensed staff and CNAs). Thus the 5-month cost to prevent pressure ulcers, in one high-risk resident, was $2,875.65."

A study of **95 long-term care facilities** participated in the *National Pressure Ulcer Long-Term Care Study* with 1,524 residents aged 18 and older, with length of stay of 14 days or longer, who did not have an existing PU but were at risk for developing a PU, as defined by the Braden Scale for Predicting Pressure Score Risk score of 17 or less on entry, concluded:[8]

"29% of residents (n=443) developed a new PU. To decrease the likelihood of an at-risk patient developing a new PU, estimates of labor to decrease likelihood of the patient developing a new PU were: RN 0.25 hours/day; nurses' aid 2 hours / day, and LPN turnover rate < 25%.

"Among high-risk patients, the incidence of pressure ulcers is estimated to be **14/1000 patient-days**. Therefore, given just 25 high-risk patients, 10 patients will develop pressure ulcers, which may be only marginally reimbursable. Pressure ulcers in the nursing home are **common problems associated with significant morbidity and mortality.**

"**17% - 35%** of patients have pressure ulcers at the time of admission to a nursing home, and the prevalence of pressure ulcers among nursing home residents ranges from **7% to 23%**."

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[6] *Ann Internal Med*. 1995 Sep 15;123(6):433-42.
[7] Sree, V., et al., "Towards understanding pressure ulcer formation: Coupling an inflammatory regulatory network to a tissue scale finite element model," *Mechanics Research Communications,* Vol 97, April 2019, pages 80-88.
[8] Horn, S., et al., "The National Pressure Ulcer Long-Term Care Study: Pressure Ulcer Development in Long-Term Care Residents," *J Am Geriatr Soc.* 2002 Nov;50(11):1816-25.

Hospitals

"It has been documented that hospital admissions due to PU are 75% higher than admissions for any other medical conditions and that, the consequences of PU development in hospitalized patients are particularly serious."[9] Therefore, pressure ulcers are a significant issue for hospitals:[10,11]

> "A total of 53,923 patients were included. The incidence of hospital-acquired pressure ulcers (HAPU) was 0.98 per 1,000 days."

The National Pressure Ulcer Long-Term Care Study: Pressure Ulcer Development in Long-Term Care Residents, states:[8]

> "The total number of patient encounters studies was 12,654. The number of patients who developed an HAPU during their ICU stay was 735 (5.81% of the incidence rate). **HAPUs are painful and costly complications of hospital care**."

Potential Lawsuits / Penalties:[12]

> "Each year, there are more than 17,000 pressure ulcer-related lawsuits filed (second only to wrongful death lawsuits), further adding to the expense of pressure ulcers.
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> "Under the Affordable Care Act, Medicare penalizes hospitals 1 percent of the reimbursement if they have high hospital acquired infection rates (including pressure ulcers."

EZTREK™ is designed to uniquely, specifically treat disorders of impaired delta-6 desaturase / inflammation. No modality of patient treatment for pressure ulcers will be optimized without understanding and improving patients' EFA-based metabolic pathways; in particular, the significance of compensating for an impaired D6D pathway, and optimizing PGE_1 output. Lipids are the #1 (modifiable) variable in tissue composition with potential to impact healing.[13,14]
Therefore, prevention and healing CVD-related disorders, wound healing, and maximizing functionality and integrity of epithelial (skin) tissue, are all expedited with continued **EZTREK**™ use.

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[9] Buh, A, et al., "Effects of implementing pressure ulcer prevention practice (PUPPG) in the prevention of pressure ulcers among hospitalized elderly patients: a systematic review protocol," *BMJ Open*, 2021;11:e043042.

[10] Kim, J, et al., "Risk factors for newly acquired pressure ulcer and the impact of nurse staffing on pressure ulcer incidence," *Journal of nursing management*, December 2019, (special issue paper).

[11] Hyun, S., et al., "Prediction model for hospital-acquired pressure ulcer development: retrospective cohort study," *JMIR Med Inform*, 2019;7(3):e13785.

[12] https://www.beckershospitalreview.com/quality/4-direct-and-indirect-costs-of-pressure-ulcers.html

[13] E. Wainwright, Y. S. Huang, et al., "The effects of dietary n-3/n-6 ratio on brain development in the mouse: a dose response study with long- chain n-3 fatty acids," Lipids, vol. 27, no. 2, pp. 98–103, 1992; W. E. M. Lands, et al., "Quantitative effects of dietary polyunsaturated fats on the composition of fatty acids in rat tissues," *Lipids*, vol. 25, no. 9, pp. 505–516, 1990.

[14] C.V. Felton, et al., "Relation of Plaque Lipid Composition and Morphology to the Stability of Human Aortic Plaques," *Arteriosclerosis, Thrombosis, and Vascular Biology*," Vol. 17, No. 7, 1997, pp. 1337-1345.