Clarification from the American Nurses Association on the Nurse's Role in Pressure Ulcer Staging ©

Courtney H. Lyder, ND, GNP, FAAN; Diane L. Krasner, PhD, RN, CWCN, CWS, BCLNC, MAPWCA, FAAN; and Elizabeth A. Ayello, PhD, RN, ACNS-BC, ETN, CWCN, MAPWCA, FAAN

Since the Centers for Medicare and Medicaid Services (CMS) selected pressure ulcers as one of the present-on-admission conditions, there have been several questions and concerns about whether nurses who are not “CMS-defined” providers can stage pressure ulcers. Because pressure ulcers are now a medical diagnosis, nurses have been asking whether the usual practice of staging pressure ulcers was now beyond the scope of nursing practice. To help clarify this question, Courtney H. Lyder, ND, GNP, FAAN; Diane L. Krasner, PhD, RN, CWCN, CWS, BCLNC, MAPWCA, FAAN; and Elizabeth A. Ayello, PhD, RN, ACNS-BC, ETN, CWCN, MAPWCA, FAAN, wrote the following letter to the American Nurses Association (ANA). The letter’s authors are delighted to share the response received from the ANA.

Letter to the ANA
July 13, 2009
Debbie D. Hatmaker, PhD, RN, SANE-A
First Vice President
ANA Board of Directors
Dear Dr Hatmaker,

As thought leaders in wound care, we seek to clarify the answer to one of the most commonly asked questions by clinicians as a result of CMS selection of pressure ulcers as one of the original 8 hospital-acquired conditions for non-higher DRG payment. Thus, on October 1, 2008, in order for the hospital to qualify for payment, the pressure ulcer must be documented as present on admission (POA). CMS has stated that, for billing compliance, the “provider” (MD or any qualified healthcare practitioner legally accountable for establishing a patient’s diagnosis, available at www.cms.hhs.gov/HospitalAcqCond/04_Reporting.asp#TopOfPage) must document pressure ulcers (location/site [codes 707.01-09] and stage [codes 707.20-25]) on admission to the hospital.

Nonprovider nurses, which depending on each US state’s defined nurse practice act may include master’s-prepared clinical nurse specialists, as well as staff nurses, do not have the legal authority to establish a medical diagnosis. The lack of clarity is that nurses do have the legal [authority] and ability to establish a nursing diagnosis. There is no nursing diagnosis that specifically states pressure ulcers; instead, it implies pressure ulcers when it states the following 3 NANDA-approved diagnoses:
- skin integrity, impaired
- skin integrity, risk for impaired
- tissue integrity, impaired.

As pressure ulcers are now both an ICD-9 [International Classification of Diseases, Ninth Revision] medical diagnosis as well as potentially a nursing diagnosis, we wish to ascertain clarification as to whether nonprovider nurses are practicing beyond their scope of practice when they document in the patient’s medical record the existence and stage of a pressure ulcer BEFORE a CMS provider (as defined above) documents their assessment of the existence and stage of the pressure ulcer.

We appreciate your assistance in helping nurses to understand this important issue and its implications for documentation and practice. We would be happy to discuss with you further this issue and are available for a meeting (either via phone or in person) to discuss our concerns as well as to answer any questions you might have. Thank you and we look forward to your timely response.

~Courtney H. Lyder, ND, GNP, FAAN
Dean and Professor, School of Nursing,
Assistant Director of Academic Nursing,
Ronald Reagan UCLA Medical Center,
Los Angeles, California

~Diane L. Krasner, PhD, RN, CWCN, CWS, BCLNC, MAPWCA, FAAN
Wound & Skin Care Consultant
York, Pennsylvania

~Elizabeth A. Ayello, PhD, RN, ACNS-BC, ETN, CWCN, MAPWCA, FAAN
Faculty, Excelsior College School of Nursing
Senior Advisor, John A. Hartford Institute of Geriatric Nursing
Clinical Associate Editor, Advances in Skin & Wound Care
Executive Editor, World Council of Enterostomal Therapists; and
Cosecretary of the World Union of Wound Healing Societies

Response from the ANA
November 11, 2009
Dear Colleagues,

We appreciate your concern and interest in the issues surrounding assessment of patients admitted to acute care facilities and documenting the status of their skin integrity. ANA’s Standards of Nursing Practice for the profession identify the following:

Assessment: The registered nurse (RN) collects comprehensive data pertinent to the patient’s health or situation.
- Diagnosis: The RN analyzes the assessment data to determine diagnoses or issues.
- Outcomes identification: The RN identifies expected outcomes for a plan individualized to the patient or the situation.
The persistence of Apligraf cells on the wound and the safety of this device in venous ulcer patients beyond 1 year and diabetic foot patients beyond 6 months have not been evaluated. Apligraf is indicated for use with standard therapeutic compression for the treatment of noninfected partial- and full-thickness skin ulcers due to venous insufficiency of duration greater than 1 month that have not adequately responded to conventional therapy. Apligraf is also indicated for use with standard diabetic foot ulcer care for the treatment of full-thickness neuropathic diabetic foot ulcers of greater than 3 weeks duration that have not adequately responded to conventional ulcer therapy and that extend through the dermis, but without tendon, muscle, capsule or bone exposure. Apligraf should not be used on infected wounds, or on patients with hypersensitivity to any components of Apligraf or the shipping medium. Please consult complete prescribing information for a description of epidermal and dermal elements contained in Apligraf.

Apligraf® Essential Prescribing Information

Numbers in parentheses () refer to sections in the main part of the product labeling. Device Description: Apligraf is supplied as a living, bi-layered skin substitute manufactured using neonatal foreskin keratinocytes and fibroblasts with bovine Type I collagen. (1) Intended Use/Indications: Apligraf is indicated for use with standard therapeutic compression in the treatment of uninfected partial and/or full-thickness skin loss ulcers due to venous insufficiency of greater than 1 month duration and which have not adequately responded to conventional ulcer therapy. Apligraf is indicated for use with standard diabetic foot ulcer care for the treatment of full-thickness foot ulcers of neuropathic etiology of at least three weeks duration, which have not adequately responded to conventional ulcer therapy and extend through the dermis but without tendon, muscle, capsule or bone exposure. (2) Contraindications: Apligraf is contraindicated for use on clinically infected wounds and in patients with known allergies to bovine collagen or hypersensitivity to the components of the shipping medium. (3, 4, 5, 8) Warnings and Precautions: If the expiration date or product pH (6.8-7.4) cannot be within the acceptable range, DO NOT OPEN AND DO NOT USE the product. A clinical determination of wound infection should be made based on all of the signs and symptoms of infection. (4, 5) Adverse Events: All reported adverse events, which occurred at an incidence of greater than 1% in the clinical studies are listed in Table 1, Table 2, and Table 3. These tables list adverse events by body system and may be attributed to treatment. (6) Maintaining Device Effectiveness: Apligraf has been processed under aseptic conditions and should be handled observing sterile technique. It should be kept in its tray on the medium in the sealed bag has been processed under aseptic conditions and should be handled observing sterile technique. It should be kept in its tray on the medium in the sealed bag until ready for use. Apligraf should be placed on the wound bed within 15 minutes of opening the package. Handling before application to the wound site should be minimal. If there is any question that Apligraf may be contaminated or compromised, it should not be used. Apligraf should be placed on the wound bed within 15 minutes of opening the package. Handling before application to the wound site should be minimal. If there is any question that Apligraf may be contaminated or compromised, it should not be used. Apligraf should not be used beyond the listed expiration date. (9) Use in Specific Populations: The safety and effectiveness of Apligraf have not been established in pregnant women, acute wounds, burns and ulcers caused by pressure. Patient Counseling Information: VLU patients should be counseled regarding the importance of complying with compression therapy or other treatment, which may be prescribed in conjunction with Apligraf. DFU patients should be counseled that Apligraf is used in combination with good ulcer care including a non-weight bearing regimen and optimal metabolic control and nutrition. Once an ulcer has healed, ulcer prevention practices should be implemented including regular visits to appropriate medical providers. Treatment of Diabetes: Apligraf does not address the underlying pathophysiology of neuropathic diabetic foot ulcers. Management of the patient’s diabetes should be according to standard medical practice. How Supplied: Apligraf is supplied sealed in a heavy duty, heavy-duty, air atmosphere and agarose nutrient medium, ready for single use. To maintain cell viability, Apligraf should be kept in the sealed bag at 68°F - 73°F (20°C - 23°C) until use. Apligraf is supplied as a circular disk approximately 75 mm in diameter and 0.75 mm thick. (8) Patent Numbers: 4,485,096; 5,106,949; 5,536,656.

Apligraf is a registered trademark of Novartis Pharmaceuticals Inc. © 2017 Organogenesis, Inc. All rights reserved.

www.apligraf.com

© American Nurses Association. ANA letter and quoted material from ANA’s Nursing Scope & Standards of Practice, printed with permission from the American Nurses Association. ANA letter is intended for general information purposes only and is not intended to provide and does not constitute legal advice.