

Medicare Coverage Advisory Committee

Usual care of Chronic Wounds

Chronic Wounds-General Overview

- Chronic Wounds and its impact on the U.S. Population.
- CMS' National Coverage Decisions on wound care therapy.
- Problems encountered in the literature evaluating the treatment of chronic wounds.
- Goals as well as questions for MCAC.

Chronic Wounds

- Definition-CMS defines chronic wounds as wounds taking longer than 30 days for complete healing.
- For the purposes of this meeting, the wounds under consideration are:
 - Venous ulcers
 - Pressure ulcers
 - Diabetic ulcers.

Epidemiology and Impact on U.S. Population

- 6 Million chronic wound patients in the U.S., this represents 2% of the population.
- \$8.5 billion for wound care products and services.
- Treating chronic wounds costs the U.S. health care system \$20 billion to \$25 billion a year.

Epidemiology (cont.)

- 15 % of the elderly population suffers from chronic wounds.
- 2% of ulcers are caused by diabetes.
- While the number of patients with pressure ulcers is increasing by 5 percent annually, the incidence of diabetic foot ulcers is growing at a rate of 14% per year and accounts for 80% of all chronic wound costs.

Chronic Wounds

- Allan et al. noted that the prevalence of reported cases of chronic skin lesions:
120 per 100,000 persons 45 to 64 years of age,
150 per 100,000 persons 65 to 74 years of age,
800 per 100,000 persons 75 years of age and older.

Allman RM. Epidemiology of pressure sores in different populations. Decubitus 1989;2(2):30-6.

Venous Ulcers

- Venous ulcers (also known as venous insufficiency ulcers, stasis ulcers, or varicose ulcers) accounts for 75- 80% of ulcers found on the lower leg.
- The incidence of venous ulcers in the U.S. is approximately 600,000 cases annually. The recurrence rate is up to 90%.

Pressure Ulcers

- Based on a MedPar data study, estimated between 1.0 to 1.7 million annual pressure ulcers.
- Some authorities place the number as high as 4.5 million.
- 500,000 to 1 million are stage II or greater.
- The estimated cost for treatment of pressure ulcers is between \$5 billion and \$8.5 billion per year.

Beckrich, Aronovitch. Hospital-Acquired Pressure Ulcers: A Comparison of Cost in Medical vs. Surgical Patients. Nursing Economics. Sept/Oct. 1999.

Pressure Ulcers

- 3% to 10% of the hospitalized population have a pressure ulcer, and 2.7% will develop a new pressure ulcer while in the hospital.
- Two thirds of pressure ulcers that develop in hospitalized patients occur in elderly patients.

Pressure Ulcers

- In spinal cord-injured patients, the incidence of pressure ulcers is approximately 8% annually, and 25% to 85% develop a pressure ulcer at some time.
- Patients with pressure ulcers are important users of medical resources. They require 50% more nursing time, remain hospitalized for significantly longer periods, and are associated with higher hospital charges.

Conn's Current Therapy 2005, 57th ed.

Pressure Ulcers

- The incidence of hospitalized patients with pressure ulcers ranges from 2.7% (Gerson, 1975) to 29% (Clarke, 1988).
- Patients in critical care units have an increased risk of pressure ulcers, as evidenced by a 33% incidence (Bergstrom, Demuth, Braden 1987).

Gerson, 1975. International Jnl. Of Nursing Studies.12,201-204.

Clarke, Kadhon. J Adv Nursing. 1988: May;13(3):365-73.

Bergstrom, Demuth, Braden. Nurs Clin North Am. 1987 Jun;22(2):417-28.

Pressure Ulcers

- These ulcers add an estimated burden of over \$1 billion in expenditures and an additional 2.2 million Medicare hospital days to the U.S. healthcare system (Staas, 1991).
- The cost of treatment ranges from \$2,000 to \$40,000 per pressure ulcer (Bergman, 1994).

Pressure Ulcers

- Studies indicate that length of stay for patients who develop pressure ulcers while in the hospital is 2 to 5 times the typical length of stay for patients who don't develop pressure ulcers while in the hospital.

Beckrich, Aronovitch. Hospital-Acquired Pressure Ulcers: A Comparison of Cost in Medical vs. Surgical Patients. Nursing Economics. Sept/Oct. 1999.

Diabetic Ulcers

- There are an estimated 18 million people in the U.S. with diabetes.
- Every year 5% of persons with diabetes will develop foot ulcers and 10-30% with foot ulcers will eventually require amputation.
- Even with successful therapy resulting in ulcer healing, the recurrence rate in that patient population is 66%.

Diabetic Ulcers

- Foot problems have been estimated to be responsible for 15% of the hospital admissions and 25% of the hospital bed usage among diabetic patients.
- The annual cost for limb amputation that are related to diabetes amount to more than \$350 million.

Cohen and Powderly: Infectious Dis. 2nd ed. 2004.

Diabetic Ulcers

- 80% - 85% of lower extremity amputations are preceded by foot ulcers (Pecoraro, Reiber, Burgess, 1990).
- Of all amputations in people with diabetes, 60% are preceded by an infected ulcer.
- In cohorts that develop ulcers, 12% to 19% require lower extremity amputation within 3-5 years, and the 3-year survival rate after one major lower extremity amputation is only 50%. The 5-year survival is only about 40% (ADA, 1996).

Diabetic Ulcers

- 15% of all diabetic patients may be expected to develop foot ulcers during their lifetime.
- Non-healing ulcers may become infected ulcers and may lead to amputations-which is 15 times more likely in diabetics than non-diabetics.
- Once amputation occurs, 50% of patients with amputation will develop an ulcer in the contra-lateral limb within 18 months of the amputation

Reiber, Boyko, Smith. Lower-extremity foot ulcers and amputations in diabetes. In: *Diabetes in America, Second Edition*. Bethesda, MD: National Institutes of Health, 1995:409-28. NIH Publication No. 95-1468.

Current NCDs on Chronic Wound Care

- Hyperbaric Oxygen Therapy for Hypoxic Wounds and Diabetic Wounds of the Lower Extremities (NCDM 20.29)

Diabetic wounds in lower extremities-The evidence is adequate to conclude that HBO therapy is clinically effective and, thus, reasonable and necessary in the treatment of certain patients with limb-threatening diabetic wounds of the lower extremity.

Hyperbaric Oxygen Therapy for Diabetic Wounds of the Lower Extremities (NCDM 20.29)

- Medicare has issued a national coverage determination for HBO therapy in the treatment of diabetic wounds of the lower extremities in patients who meet each of the following criteria:
 1. Patient has Type I or II diabetes, and has a lower extremity wound that is due to diabetes;
 2. Patient has a wound classified as Wagner grade III or higher; and
 3. Patient has failed an adequate course of standard wound treatment.

Electrostimulation for Wounds (NCDM 270.1.1)

- Medicare allows for coverage for the use of electrical and electromagnetic stimulation for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous ulcers. All other uses of electrical and electromagnetic stimulation for the treatment of wounds are non-covered.
- Electrical stimulation and electromagnetic stimulation for the treatment of wounds will not be covered as an initial primary treatment modality.

Autologous Blood-Derived Products for Chronic Non-Healing Wounds (NCDM 270.3)

- CMS has determined that the evidence is adequate to conclude that autologous platelet-derived growth factor (PDGF) in a platelet poor plasma does not improve healing in chronic non-healing cutaneous wounds, and therefore, is not reasonable and necessary.

Non-Contact Normothermic Wound Therapy (NNWT) (NCDM 270.3)

- There is insufficient scientific or clinical evidence to consider this device as reasonable and necessary for the treatment of wounds

Treatment of Decubitus Ulcer (NCDM 270.4)

- Hydrotherapy (whirlpool) treatment for decubitus ulcers is a covered service under Medicare for patients when treatment is reasonable and necessary. Some other methods of treating decubitus ulcers, the safety and effectiveness of which have not been established, are not covered under the Medicare program.

Porcine Skin and Gradient Pressure Dressings (NCDM 270.5)

- Porcine (pig) skin dressings are covered, if reasonable and necessary for the individual patient as an occlusive dressing for burns, donor sites of a homograft, and decubiti and other ulcers.

Pneumatic Compression Devices (NCDM 280.6)

Pneumatic compression devices are covered in the home setting for the treatment of Chronic Venous Insufficiency of the lower extremity only if the patient has one or more venous stasis ulcer(s) which have failed to heal after a six month trial of conservative therapy directed by the treating physician. The trial of conservative therapy must include a compression bandage system or compression garment, appropriate dressings for the wound, exercise, and elevation of the limb.

Usual Care?

- Though CMS policies require usual care prior to adjunct therapy, we find many inconsistencies in how “usual care” is defined in clinical practice.
- Define usual care
 - Debridement
 - Cleansing
 - Dressing
 - Compression
 - Antibiotics
 - Off-loading

Problems in evaluating the evidence

- Lack of blind assessment of outcomes
- Inadequate sample size
- Lack of documentation of base-line data
- Duration of study too short
- Lack of documentation of recurrence and adequate follow-up
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Problems in evaluating the evidence

- Paucity of data, methodological flaws, defining outcomes

A Cochrane Collaboration project “Filling the gap in the body of knowledge as to the local treatment of poorly healing wounds” 2004, concluded that “even though Systematic Reviews are available, evidence is strikingly scarce regarding local wound care, although this is a worldwide problem. In order to fill the gap in “the body of knowledge” as to local wound care, the development and conduction of good methodological RCTs (which are the basis of SRs) is encouraged. The results of such trials might help to guide physicians and nurses in choosing the optimal wound care products.”

Previous Technology Assessments of Chronic Wounds

- The UK NHS R&D Health Technology Assessment Programme published a set of comprehensive technology assessment reports on the management of chronic wounds between 1997 and 2000.
- Purpose-to provide a comprehensive review of the evidence of different wound care interventions.
- Systematic review of treatments for chronic wounds assessing the efficacy.
- The TA did not make a specific recommendation for standard of care.

UK NHS R&D Health Technology Assessment Programme on Chronic Wound Care

- The analysis concluded that there is little evidence to indicate which dressings or topical agents are the most effective in the treatment of chronic wounds.

Problems in evaluating the evidence

- A Cochrane analysis “Dressings and topical agents for leg ulcers” by Bradley 2005 note “There is insufficient evidence to determine whether the choice of topical dressings affect the healing of leg ulcers. Inadequate description of the people in the clinical trials means that the results cannot be easily applied to other clinical populations.”

<http://www.cochrane.org/cochrane/revabstr/AB001836.htm>

Draft FDA Guidance Document, 2000

- Provided guidance on study design and related issues for the industry developing products for treatment of venous stasis ulcers, diabetic foot ulcers, pressure ulcers and burn wounds.
- The draft document also provided recommendations about labeling claims, outcome measures, trial design as well as special considerations for preclinical development.
- The document represented a view of only one governmental agency, and was not intended to provide recommendations for routine clinical practice.

Problems in evaluating the evidence

- O'Meara et al. Systematic reviews of wound care management: antimicrobial agents for chronic wounds; diabetic foot ulceration. DARE abstract 200118087-to assess the clinical and cost-effectiveness of antimicrobial agents in the prevention and healing of chronic wounds.

O'Meara S, Cullum N, Majid M, Sheldon T. Systematic reviews of wound care management: antimicrobial agents for chronic wounds; diabetic foot ulceration. DARE abstract 200118087.

Problems in evaluating the evidence

- Results-several methodological problems were identified; the most common was an inadequate sample size.
- Conclusion: there is no existing evidence to support the use of systemic antimicrobial agents for chronic-wound healing. The author states that most of the research conducted in this area needs replication with well-designed randomized controlled trials.

Gaps in Treatment Options for Non-healing Wounds

Recommendations

- Research designs should collect outcomes data on large groups of long-term care patients and retrospectively analyze the data in an attempt to identify healing profiles.
- The establishment of a validated tool or process by which all clinicians can reliably determine the value of non-healing endpoints.

Alvarez, Meehan, Ennis, Thomas, Ferris, Kennedy, et al. Chronic Wounds Palliative Management for the frail population. Wounds a Compendium to Clinical Research and Practice. Vol 14, number 8. October 2002.

<http://www.o-wm.com/wnds/frailsup4.cfm#>

Problems in evaluating evidence pertaining to wound care treatments

- Standards that are universally applied.
- Establishment of non-healing endpoints in product and treatment testing.

Alvarez, Meehan, Ennis, Thomas, Ferris, Kennedy, et al. Chronic Wounds Palliative Management for the frail population. Wounds a Compendium to Clinical Research and Practice. Vol 14, number 8. October 2002.

<http://www.o-wm.com/wnds/frailsup4.cfm#>

Chronic Wound Care

- Though these are listed as components of usual care, there is no agreement as to what “usual care” is:
 - Debridement
 - Cleansing
 - Dressing
 - Compression
 - Antibiotics
 - Off-loading

Goals

- Identify current problems with the literature on the evidence of chronic wound care.
- Define baseline of what good care is for the treatment of chronic wounds so that CMS can develop standards for evidence for future NCDs.
- Define evidence standards for future evaluations
- Improve health outcomes for Medicare beneficiaries.

Questions for the MCAC Committee

1. Usual care for chronic wounds commonly includes debridement, cleansing, dressing, compression, antibiotics, and off-loading.
 - a. Is there sufficient evidence to assess the benefit of these modalities?
 - b. Are there other modalities that provide benefit?

Questions for the MCAC Committee

2. The following outcomes are commonly used to assess healing of chronic wounds:
 - Complete healing
 - Partial healing rate
 - Recurrence rate
 - Elimination of infection
 - Amputation rate
 - Reduction of pain
 - Resumption of normal activity
- a. Are these appropriate outcomes to be considered to assess the benefits of usual care of chronic wounds?
- b. Are there other outcome measures that should be considered?
- c. As new technologies arise, are new endpoints needed to demonstrate a benefit in the treatment of chronic wounds?

Questions for the MCAC Committee

3. Based on evidence reviewed, how likely is it that the treatments discussed in Question 1 will positively affect the outcomes discussed in Question 2?
4. Based on the evidence reviewed, do the treatments reviewed in Question 1, singly or in combination produce clinically significant net health benefits in the treatment of chronic wounds?
5. Based on the evidence reviewed, how likely is it that usual care used to treat chronic wounds can be generalized to:
 - a. The Medicare population (aged 65+)?
 - b. Providers (facilities/physicians) in community practice?

Questions for the MCAC Committee

6. What are the knowledge gaps in current evidence pertaining to the usual care of chronic wounds?
7. What trial designs will support the development of sufficient evidence to determine the appropriate treatment of chronic wounds?
What units of analysis and covariates can be considered?