BRINGING INNOVATION TO PATIENT CARE WORLDWIDE

Advanced Wound Management:

Healing and Restoring Lives

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New wound care technologies are being developed at an increasingly rapid pace in recent years. These innovations could significantly reduce the overall costs for treating complex and chronic wounds, while offering greater savings in preventing wounds and their recurrence.

This progress will prove invaluable as the average age of Americans increases, through resolving the frequent healing complications faced by the elderly, whose thinner layers of skin make them more vulnerable for greater risk from wounds. Other demographic trends will likely boost the incidence of wounds, particularly the growing number of people with diabetes, which has toughly tripled in the past two decades. Thousands of these people face complications of foot ulcers and risk amputations due to complications and infections resulting from diabetes. Recent research predicts that the incidence of chronic and complex wounds could rise from five to seven million cases.

The ultimate goal of wound management is the prevention of wounds, or the halting of wound deterioration to achieve more rapid healing. This goal can only be accomplished by intervening with appropriate quality care, in a timely manner.

Coverage and reimbursement policies in the nation’s Medicare system currently do not reflect technological advances in wound care management, are not comprehensive, and can cause disruptions in delivering appropriate care to patients. Medicare often focuses narrowly on a specific unit cost or the cost of wound care at a specific site, while not considering the long-term costs of caring for patients.

Expenses related to wound care may include surgical and diagnostic procedures, pharmaceuticals, and fees for services provided by physicians and other health care professionals. Other costs include the use of medical equipment, the use of devices to provide compression or support for surfaces, wound closing, and the cost of skin care protection products, compression bandages, and changing dressings.

Delays in wound treatment may result in even higher expenses for hospital or nursing home stays, physician services, surgical procedures, diagnostic tests, pharmaceuticals, clinic or home health visits, and charges for use of medical supplies and equipment. Management and treatment of chronic and complex wounds costs the nation an estimated $20 billion annually.

AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Its members produce nearly 90 percent of the health care technology purchased annually in the United States, and more than 50 percent of the total purchased annually around the world.

We recognize that the treatment of chronic and complex wounds represents a significant financial burden on the health care system and the economy as a whole. In 2003, U.S. expenditures for specialty dressings, devices and topical treatments for chronic and complex wounds exceeded $1.7 billion. These costs exclude the additional costs to society in terms of lost workdays or productivity.

This paper has been developed to explain the challenges facing patients as they seek to access the most appropriate, and often cost-saving, wound care. Moreover, this paper highlights the challenges that physicians and other health care professionals face as they strive to provide the best possible care across clinical settings with coverage, coding and reimbursement policies that do not adequately consider the technological advances in wound care treatment.

AdvaMed Advanced Wound Management Recommendations

AdvaMed encourages the adoption of cost-effective wound-healing approaches for chronic and complex wound management.

The following recommendations need to be considered by public policy makers to provide patients with access to the most appropriate therapies to care for their wounds and provide the greatest long-term value:

- Increase the wound care supply allocation in the Medicare prospective payment systems (PPS) for skilled nursing facilities, home health
services and hospital outpatient clinics to encourage the appropriate use of advanced technologies for wound management.

- Revise the PPS for skilled nursing facilities to reflect the incremental cost for the necessary treatment and therapy of a wound when it is not the primary diagnosis.

- Allow for physician billing and reimbursement for wound dressings and supplies, using the Healthcare Common Procedure Coding System (HCPCS) codes, when providing services in the physician’s office.

- Provide coverage for wound-related Durable Medical Equipment (DME) in nursing facilities for prevention and treatment of chronic wounds.

- Provide coverage within the Medicare Part B Surgical Dressing Benefit for preventive and early intervention technologies for tissue damage.

- Update the Medicare Surgical Dressing Policy categories and associated fees to reflect the performance of the dressing rather than the composition.

- Expand the Medicare Surgical Dressing Policy to include a new category for antimicrobial barrier dressings.

- Revise the Nursing Home Minimum Data Set (MDS) and Home Health Care Outcome and Assessment Information Set (OASIS) assessment tools to better identify all wound types, consistently stage and assess pressure ulcers, consistently account for management and treatment, and adequately reimburse for care.

- Surgical dressings and support surfaces should not be incorporated into the Medicare Durable Medical Equipment, Prosthetics and Orthotics (DMEPOS) Competitive Acquisition Program.

- Provide Medicare coverage for compression technologies for healed venous leg ulcers in order to reduce recurrence rates, thus reducing overall treatment costs.

- Expand Medicare coverage policies for new advanced wound therapies to encourage consistent treatment planning as the patient moves through the health care system.

- Support a more aggressive approach to the treatment of chronic wounds allowing for the appropriate therapies to be used early in the treatment plan to control overall cost of wound care, rather than have treatment plans to reduce price by line item.
I. Advanced Wound Management: Bringing Patients the Best Care

Everyone will experience some type of wound in their lifetime. Most wounds are due to small injuries and heal quickly, with very little attention. However, many people suffer from chronic or complex wounds that can be very difficult to heal and cause severe pain and hardship. Each year between five and seven million chronic and/or complex wounds occur.

Chronic and complex wounds can lead to complications such as infection, pain, depression and limb amputation. Patients affected by these types of wounds often require additional help performing common daily tasks and face higher mortality rates.1,2 Billions of dollars each year are spent to care and treat these wounds.

Patients need access to the “best standard” of care to heal their wounds, prevent complications and restore quality of life. This is the goal of health care providers and is cost-effective for the health care system.

The treatment of chronic and complex wounds is a significant burden on the health care system and on the economy as a whole. In 2003, over $1.7 billion was spent just on specialty dressings, devices and topical treatments for chronic and complex wounds (this figure excludes expenditures on gauze dressings).3 The annual costs for overall management of these wounds is over $20 billion, not including the additional costs to society in terms of lost workdays or productivity.4,5

Clinicians treating chronic and complex wounds must be able to provide the best possible care. Those responsible for making and administering wound care policies need to understand the full effects of their decision-making. Effective wound care policy must take a holistic approach and a comprehensive view of costs.

OVERVIEW

In an attempt to contain health care costs, Medicare policies concerning wounds have created situations that can disrupt appropriate care delivery across clinical settings. Some policies limit providers from using best-practice wound care and continuation of therapy across care settings. Inadequate payment encourages the use of less expensive but ultimately more costly care approaches. Recently, Medicare included wound dressings and support surfaces in the DMEPOS Competitive Acquisition Demonstration Projects. Inclusion of these technologies in Competitive Bidding may further reduce patient access to effective wound care technologies.

Medicare coverage and payment for modern, moist-wound care dressings in most care settings is underpaid.

In the original Medicare fee-for-service model of payment, providers were reimbursed for the actual amount of services and supplies that were used to deliver care. Today, the Medicare Prospective Payment Systems (PPS), which reimburse providers for care delivery, include the cost of wound dressings in the payment structure. However, these systems fail to adjust for the level of use. Most PPS systems assign a fixed rate amount for supplies, including wound dressings. This fixed dollar amount is applied to all wound types regardless of clinical need or utilization. Hence, a patient with a small, uncomplicated wound is allocated the same amount of funds for their wound dressings as a person with a large, complicated wound.

Medicare coverage policies for wound care therapies and advanced technologies are inconsistent. Medicare does not consistently provide for advanced wound care treatments needed.
for some wounds in the PPS payment structures. In some cases, providers have less available resources to manage chronic wounds. In a skilled nursing facility when advanced treatment modalities such as pressure reducing support surfaces, negative pressure wound therapy devices, selective debridement, or bilayered skin substitutes are used to treat complex wounds, the cost of these advanced approaches must come out of the total prospective payment rate to the facility. However, the expense for these advanced treatment modalities is not factored into the cost calculation for supplies in the payment rate. Ironically, if a wound was treated with some of the same devices under Medicare home health services, these devices would be paid in addition to the PPS payment.

Medicare has been slow in adopting new technologies into their policies and payment systems for wound care. New dressings, devices and advanced therapies that can improve patient outcomes have not been readily available to Medicare beneficiaries. The lack of revisions and timely updates to coverage and payment policies has delayed the use of newer products, such as dressings incorporating silver for anti-microbial effects, that can have beneficial effects on healing wounds, lowering the risk of infection and reducing overall expenditures for treating complex and chronic wounds.

Current Medicare policies do not provide coverage for early wound prevention or recurrence. Medicare Part A and Part B policies lack coverage for prevention of wounds. Currently, technologies that reduce damage and breakdown of skin (for example, compression therapy devices that reduce recurrence of venous ulcer and off-loading walking devices that prevent diabetic foot ulcers) are not covered.

Improving wound care-related policies will improve the lives of patients with wounds or at risk for developing wounds.

Medicare resources are being ill-spent and patients have to suffer from wounds longer, in some cases, because of inadequate coverage for technologies that could improve the healing process. Gaps in the Medicare coverage policies for advanced wound therapies, moist-wound healing and preventive measures need to be corrected to better manage chronic and complex wounds. The current system of coverage and reimbursement in many cases has resulted in severe underpayment to providers for the appropriate, best-practice care of complex and chronic wounds.
II. The Impact of Wounds on People’s Lives

A wound can have a significant impact on a person’s life. Wounds can lead to prolonged periods of disability in addition to suffering pain and discomfort, and may even prevent a person from performing everyday activities such as walking and bathing. This inactivity may in itself lead to further health problems.

Some wounds are associated with odor and excessive drainage and require frequent attention that may impede social interactions. A non-healing wound may prevent a return to work which can have psychological as well as economic ramifications. Chronic leg wounds (ulcers) are estimated to account for the loss of two million workdays a year. The impact of resulting loss of self-esteem, continued pain and possible depression is difficult to quantify but is certainly real.

In addition to any loss of earnings, people may have to choose between a commitment to work and a commitment to medical management of their wound. With most insurance, people will have deductibles, co-payments, and additional “balance billing” (the difference between reimbursement fee and supplier price) for their Medicare benefits. If supplies are not covered by insurance or have restrictions on the amount allowed, there will also be further out-of-pocket expenditures. Other additional indirect costs may include extended stays in care facilities or travel to and from an outpatient clinic. Complications such as infections may also give rise to additional co-pays for concomitant therapy such as antibiotics.

A wound can control a person’s life. People may have to cope with specialized devices or beds, lack of mobility, dressing changes, drainage, odor, clothing limitations and sleep deprivation. These difficulties can lead to social isolation, diminished quality of life and poor body image. Healing may take months or even years, and unsuccessful wound treatment can lead to loss of a limb or even death. Sixty percent of non-traumatic lower limb amputations are associated with diabetes.
III. Wounds: Types, Incidence and Prevalence

Countless wounds occur each year but it is chronic and complex wounds that require the most skill, time and resources to heal. The *Wound Healing Society* defines a chronic wound as one that has “failed to proceed through an orderly and timely repair process to produce anatomic and functional integrity.” These wounds involve damage to underlying tissue and structures as well to the integrity of the skin itself. The most common types of chronic wound are leg ulcers, pressure ulcers and diabetic foot ulcers.

Oxygen cannot get to the tissues and as a result can cause an open wound (venous ulcer). These wounds are associated with drainage, often heavy at times, odor and pain. Recent studies have shown over 63% of people with venous ulcers experience associated pain. Oxygen cannot get to the tissues and as a result can cause an open wound (venous ulcer). These wounds are associated with drainage, often heavy at times, odor and pain. Recent studies have shown over 63% of people with venous ulcers experience associated pain.

**Venous Leg Ulcer**

复杂伤口是伤口，伴随并发症和烧伤。皮肤通常发生在外露骨隆起部位。复杂伤口可能涉及几个部分的皮肤，这使得伤口愈合变得困难。

**Wound Types**

*Leg Ulcers:*

Leg ulcers occur due to impairment of the circulation in the leg. The ulcer can be large enough to surround the whole leg and can take from several months to over a year to heal.

A leg ulcer can be venous or arterial. A venous ulcer occurs when there is damage to the small valves in the veins, which help blood flow. The blood cannot flow freely and begins to collect in the veins. This increases pressure in the veins and eventually fluid leaks into the tissues surrounding the veins.

**Pressure Ulcers:**

Pressure ulcers generally occur when a person is immobilized. Sustained pressure eventually can reduce circulation and oxygen delivery to the skin. The tissue becomes damaged forming a wound (ulcer). This usually occurs over a bony prominence. Pressure ulcers can involve minimal or extensive...
damage to the layers of the skin and even bone or tendon. More than half of all people with a pressure ulcer report experiencing pain.\textsuperscript{12}

\textbf{Pressure Ulcers}

\textbf{Over two million pressure ulcers occur each year with an annual cost greater than $1.3 billion.\textsuperscript{13} Despite the recent national declines in the prevalence of pressure ulcers, these wounds remain a significant burden both in terms of human suffering and economic consequences.}

Older individuals are very susceptible to skin breakdown due to the thinning of the top layers of the skin (epidermis and dermis), and elderly patients admitted to hospital are at particularly high risk for development of pressure ulcers.

- 2/3 of people admitted to a hospital with a femoral fracture develop a pressure ulcer
- 1/3 of people admitted to a critical care unit develop a pressure ulcer\textsuperscript{13}
- Nearly 15\% of hospitalized patients age 65 or older developed a pressure ulcer during a 5-day stay or longer\textsuperscript{14}

Pressure ulcers can also result from lying on an operating table for a prolonged time or being immobilized after surgery. Development of pressure ulcers following surgery is common. Pressure ulcers are also seen in people at home: up to one-fifth of all home health service visits involve care of a pressure ulcer, and more than one-third of people with spinal cord injuries develop pressure ulcers.\textsuperscript{15}

\textbf{Diabetic Foot Ulcers:}

Persons with diabetes are prone to foot ulcers because they usually have sensory, motor and nerve damage. A loss of pain sensation prevents them from sensing that they have sustained a foot injury, which may result from a single traumatic event, such as stepping on a tack or bathing feet in excessively hot water.

Persons with diabetes are at high-risk for wound infection due to their varying blood sugar levels, circulation changes and impaired local immune defenses, which predisposes them to delayed healing and to infection.

Diabetic foot ulcers are a common complication of diabetes and affect approximately 15\% of the diabetic population.\textsuperscript{16,17} Over 1.5 million foot ulcers occur annually and this number is expected to increase as the incidence of diabetes rises. Currently there are nearly 800,000 new cases every year affecting approximately 6\% of the population.\textsuperscript{18-20}

\textbf{Foot ulcer}

\textbf{Amputation due to ulcer}

Diabetic foot ulcers are a recurrent condition and lead to over 82,000 amputations annually. The direct and indirect costs of such lower extremity amputations can range from $20,000-60,000.\textsuperscript{2,7} It is critical to heal foot ulcers rapidly in order to reduce the risk of infection and avoid amputation.
Burns:

Over one million burn cases occur each year, leading to over 700,000 emergency room visits and 45,000 hospitalizations. Burns are often life-threatening, especially if large areas of the body’s surface are involved. All burns, however, are expensive and difficult to treat because of the risk of infection, dehydration and the painful nature of such wounds. For complex, extensive burns, costs increase dramatically due to the need for extended hospitalization, medications, antibiotics, and multiple surgical procedures to repair or reconstruct damaged areas. Many burn victims may require years of care and therapy to help restore them to full functionality.
IV. The Costs of Healing Wounds

Identifying costs associated with treating wounds is rarely simple. A wound can be a secondary diagnosis related to and resulting from a primary condition. Furthermore, wounds are often treated in a number of different settings (hospital, nursing facility, home health service, out-patient clinic, doctor’s office, etc.) during the course of healing, which complicates tracking all costs.

Calculating costs associated with wounds needs to take into account all care site expenditures: surgical procedures, diagnostic procedures, pharmaceuticals, as well as the physician charges. In addition, the cost of medical equipment used outside the care setting – for example, seating and compression devices, support surface devices, off-loading devices, and wound closure devices – and other supplies for dressing changes, skin care protection products and compression bandages must be included.

Research summarizing the results of 26 studies on pressure ulcers and venous leg ulcers found the cost of medical supplies (dressings and compression bandages) comprise only a fraction of the total costs of venous ulcer care. The study also concluded that purchase price per dressing was not an indication of cost effectiveness and using unit cost as a criterion for choice of local wound care may add to the financial burden of treatment.

Additional costs are incurred when wound healing is delayed, including: extended facility stays, additional physician charges and diagnostic studies, more clinic or home health visits, increased medical supply and equipment charges, added surgical procedures and pharmaceutical expenses. In general, the failure to heal chronic wounds results in innumerable societal costs which are very difficult to quantify.

Despite the complicated task of calculating the total cost of treating chronic or complex wounds, a number of estimates have been made for the overall costs as well as for specific wound types:

- The management and treatment of chronic and complex wounds costs the nation an estimated $20 billion per year.
- Pressure ulcers are associated with significant rates of morbidity and mortality. People who develop pressure ulcers often have longer hospital stays and rehabilitation times and use considerably more resources than patients who do not develop these wounds. The average hospital stay for a patient with a primary diagnosis of pressure ulcer is nearly five times greater than for patients without an ulcer.
- Medicare claims analysis shows that expenditures on diabetic patients with diabetic lower-extremity ulcers are three times as high as for Medicare patients in general.

Cost Estimates of Wound Care

**Diabetic Ulcers:**
- $60,000 avg. w/amputation (2003 costs)
- $28,000 – care for 2 years (1999 costs)
- >$44,700 with amputation (1994 costs)
- Amputation adds $15,792 to hospital costs (1998 costs)
- $6,664/episode (1994 costs)

**Pressure Ulcers:**
- $22,000 – when pressure ulcer is primary diagnosis in a hospital (1992 costs)
- $11,000 additional cost if pressure ulcer develops while in hospital for other care (1992 costs)
- $1.3 billion/year (1994 costs)
- $5 - $65,000/case – based on severity

**Leg Ulcers:**
- $2-3 billion/year
- $1 billion for out-patient care alone
- $27,000 per episode
V. Modern Approaches and Technologies in Wound Healing

The ultimate goal of wound management is the prevention of a wound or, in the case of an existing wound, the arresting of deterioration and the achievement of rapid healing. This can only be achieved by appropriate quality care intervention as early in the process as possible, including:

- Use of preventive and treatment products to reduce or relieve the physical impact of pressure.
- Adoption of “best practice” moist-wound healing as a standard of care,
- Addressing the nutritional requirements necessary to support healing, and
- Use of advanced therapies and technologies to promote healing and closure in the case of complex and non-healing wounds.

Unfortunately, many policies and reimbursement systems that affect the choice of wound care treatments have not developed according to any plan. There has been no formal system for their updating in the light of new treatments or technologies. As a result, not all stages in the wound healing and prevention continuum are covered. The true total costs of wounds and their treatment are not taken into account, and “best practices” are not, for the most part, adopted.33

Moist-Wound Healing Therapies

Best practice chronic wound care starts with moist-wound healing. Traditionally, wounds have been managed with simple gauze and gauze-like dressings to cover and protect the wound. These dressings often dry out the wound bed – destroying healthy cells – and can stick to new tissue causing damage on removal.

Moist-wound healing dressings provide an environment in the wound that supports the vital cells responsible for wound repair while preventing damage of viable tissues. Moist-wound healing dressings provide an environment that promotes cell repair and protect newly formed tissue from damage during dressing removal. Additionally, moist-healing dressings help reduce pain in the wound and during dressing changes. Moist-wound healing has been shown to provide better healing rates and has proven to be a more cost-effective approach than traditional gauze-based dressing techniques.13,32

Since the early 1980s, modern dressings have been available that are able to provide a moist-healing environment for wound management. These products can also provide a bacterial barrier to prevent invasion of infectious organisms into the wound. Standard gauze and simple gauze-like cover dressing do not provide this protection. Dressings such as alginates, hydrocolloids, foams, collagen and hydrogels are just a few of the technologies that provide this moist-healing approach. Wound care experts agree that moist-wound healing techniques should be adopted and, in fact, they have been included in a number of practice guidelines.34-36 However, despite this general consensus, the majority of chronic wounds are still covered with traditional gauze dressings.

Moist-wound healing techniques have been more widely adopted in most European countries than in the U.S. The prime reason for this is that reimbursement in the U.S. is based on unit costs of the wound dressing rather than on total costs to heal a wound. In some settings, payment systems are based on “management” rather than healing of wounds.

A recent German study showed that the cost of all the materials used for a single dressing change was slightly higher with a moist-wound healing dressing, but on a weekly basis the moist-wound healing dressings were significantly (72%) lower, due to less frequent dressing changes. The difference was much more marked when nursing time costs (also payable by the insurer) were included: €89.40 compared with €352.31.37

Many studies have reported on the cost-effectiveness of moist-wound healing as well as its clinical advantages. These studies take account of frequency of dressing changes as well as cost savings resulting...
from faster healing, lower complication and infection rates, and savings on other supplies. The importance of reducing inflammation/pain, providing a bacterial barrier and reducing infection rates as well as the achievement of faster healing rates with a variety of chronic wounds is also well documented. Wound infections complicate treatment, delay wound closure, and increase the costs of treatment. While some topical antimicrobials are toxic to cells and can delay healing, some new moist-healing dressings (in addition to providing a bacterial barrier) incorporate a safe non-toxic antimicrobial agent such as silver. Unfortunately, these newer dressings have not been reimbursed at a level that adequately accounts for their increased benefit for the wound.

Advanced Therapies

Not all complex and chronic wounds respond to moist-wound healing alone. For such cases, a number of new technologies are available to help achieve wound closure. These new alternative therapies can help to reduce time and costs to heal these extremely complex and/or non-responding wounds.

Examples of widely used advanced therapies:

Negative Pressure Wound Therapy (NPWT)
Negative pressure wound therapy (NPWT) is the controlled application of sub-atmospheric pressure to a wound using an electrical pump to convey that lessened pressure through tubing to a specialized wound dressing. The specialized wound dressing includes an occlusively sealed, resilient, open-cell foam surface dressing. The dressing helps to maintain sub-atmospheric pressure at the wound site to promote wound healing. Dressings are reapplied every 48 hours to allow less frequent dressing changes. Drainage from the wound is collected in a canister.

NPWT is used for acute and chronic wounds that have not responded to standard care or are complex and problematic. NPWT systems remove excessive fluid and debris, decrease bacteria and increase blood flow to promote rapid granulation tissue development. Use of NPWT also allows for treatment of complex wounds at home, which is more cost-effective than in a hospital or long-term care facility.

NPWT has been proved to provide improved healing and cost effectiveness in a wide range of wound types.
- 1,032 Medicare beneficiaries (w/ 1,170 wounds) that failed to heal w/ previous treatments had more than 2x greater reduction in the size of the wound with NPWT therapy, with a treatment cost that was 38% less when NPWT therapy was used.

Bioengineered Skin Substitutes act as a substitute for the damaged layers of skin, and maintain a biochemical-balance and moist-wound environment while structurally supporting tissue growth and/or providing beneficial growth factors to help heal the wound. They provide coverage for burns, venous ulcers, and diabetic ulcers that need immediate closure or that have not responded to standard care. Most bioengineered skin substitutes consist of dermal cells, epithelial cells, or both, on a scaffold of collagen or another support material. They are placed and/or sutured over the wound and have proven cost effective with hard-to-heal venous ulcers.

- Diabetic foot ulcers treated with a living, bi-layered skin substitute plus conventional therapy had 56% healed in 65 days vs. 39% healed in 90 days with conventional therapy alone (P=.0026).
- A Human Fibroblast-Derived Temporary Skin Substitute used for the treatment of burns was the focus of a 1999 clinical study by Drs. Demling and DeSanti. The study concluded that treatment with Human Fibroblast Derived Temporary Skin Substitute significantly improves the management and healing rate of partial-thickness burns, compared to standard open topical ointment technique.
- Human Fibroblast-Derived Dermal Substitute is available for the treatment of diabetic foot ulcers and Dystrophic Epidermolysis Bullosa (DEB). Diabetic foot ulcers treated with Human Fibroblast-Derived Dermal Substitute plus conventional therapy achieved 100 percent wound closure versus 18 percent with conventional therapy alone.
Electrical Stimulation is the application of an electrical current to the skin surrounding the wound at varying levels of intensity to help activate cell growth and encourage wound closure. It is used on various types of wounds. The therapy is usually given every few days by a clinician or physical therapist in a hospital, nursing facility, at home or in a doctor’s office. It is continued until significant closure of the wound is achieved.

- Patients with spinal cord injury had their pressure ulcers heal in 13 days on average with electrical stimulation vs. 31.5 days for standard wound care.45

Recombinant Growth Factor is the administration of a chemical (drug) that provides platelet-derived growth factor (PDGF), one of the key growth factors involved in tissue repair. This type of product has shown improved healing rates compared with traditional approaches to the treatment of diabetic foot ulcers.46 The gel is applied every day with alternating 12 hour dressing(s).

- 43% diabetic ulcers healed with PDGF versus 28% with standard wound care.41

Autologous Growth Factor (AGF) Therapy is the administration of a substance that delivers several growth factors linked to tissue repair to the wound. The AGF is comprised of substances that are processed from the patient’s own blood. This therapy is usually applied once per week until closure of the wound. Improved wound healing rates and rates of wound closure have been documented.

- In over 3,800 patients, more (would be preferable to put in more precise numbers)

### VELOCITY OF WOUND HEALING

<table>
<thead>
<tr>
<th>Outcome Factor</th>
<th>Study</th>
<th>Wound Type</th>
<th>V.A.C. Result</th>
<th>Standard Care Result</th>
<th>% V.A.C. Improvement</th>
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<tr>
<td>Days to Healing % Healed (in 84 days)</td>
<td>Armstrong1</td>
<td>Diabetic amputation</td>
<td>54.6%</td>
<td>40.9%</td>
<td>33%</td>
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<td>Days to Heal</td>
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<td>Mixed lower extremity</td>
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<td>158</td>
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<tr>
<td>Healing Rate</td>
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<td>Dehisced surgical</td>
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<td>Days to 75+% Granulation</td>
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<td>Reduced Hospitalization / Emergent</td>
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Unfortunately, in spite of the documented clinical advantages and cost-effectiveness of these new approaches, coverage of and payment for them has not kept pace with their clinical adoption. Advanced therapies are supported by a number of published wound care guidelines including those from the American College of Foot and Ankle Surgeons, the American Medical Directors Association and the Consortium of Spinal Cord Medicine.

Low Energy Non-Contact Ultrasound is the utilization of continuous ultrasonic energy to atomize saline and deliver a continuous mist to the treatment site to promote wound healing. The process works fosters wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudates, and bacteria. Studies have confirmed that the ultrasound energy provided during the energy non-contact ultrasound treatment has a healing effect that modifies the wound bed tissue positively to promote healing. Ennis et al. conducted a study of patients with recalcitrant diabetic foot ulcers. The study was a randomized, double-blinded, multicenter study in hospital-based and private wound care clinics.51 The results of the study revealed that wounds came to closure for 40.7% of the patients receiving low energy non-contact ultrasound as compared to the wound closures found in 14.3% of patients in the control group, which proved to be statistically significant Chi-square (p=0.22) and Kaplan Meier Wilcoxin (p=0.11).
HEALING RESULTS

Adjunctive Therapies and Devices

In addition to treatment of the wound itself, for venous ulcers adequate compression therapy is required to support blood flow back to the heart.\textsuperscript{43,44} Sustained, graduated moderate-to-high compression is “best practice” care that can lead to rapid healing of venous ulcers.\textsuperscript{6,42} Various bandaging systems, devices and stocking systems can all provide this degree of pressure. Once an ulcer is healed, the use of compression stockings to provide adequate pressure to sustain circulation is recommended to prevent recurrence of the ulcer.

In order to heal a pressure ulcer, which results from excess pressure on the skin, the pressure must be reduced to a level that allows blood flow and repair of the wound. Pressure-relieving devices, commonly referred to as support surfaces, are critical in the healing process and to prevent development of pressure ulcers in people who are at risk. However, the choice of device for many payers encourages more of a “pyramid” approach to product selection: if the patient fails to respond to one category of surfaces, a more aggressive therapy is provided. This approach is somewhat counterintuitive considering the longer it takes for a wound to heal, the greater the risk of needing additional products and services, potentially adding costs to the healing process.

Evidence-Based Wound Care

The main goals for the treatment of chronic and complex wounds are the prevention of further deterioration and optimal healing without complications. Moist-wound healing has been well established as the “gold standard” for the management of chronic wounds.

Adequate compression therapy along with moist-wound healing has been established as “best-practice” care and is the most cost-effective method for healing venous ulcers.\textsuperscript{38}

The clinical benefits and cost-effectiveness of advanced therapies such as growth factor therapy, negative pressure wound therapy, electrical stimulation, tissue and skin replacements and hyperbaric oxygen and have been established.\textsuperscript{64-85} These advanced therapies enable providers to care for and heal many of the complex and chronic wounds that did not heal with traditional wound care.

The cost-effectiveness of support surfaces for healing pressure ulcers has also been proven.\textsuperscript{46} A recent study comparing all categories of support surfaces in long-term care facilities provides clinical evidence that aggressive intervention with air fluidized therapy resulted in faster healing, reduced re-hospitalization and overall cost of treatment, especially for patients with more severe wounds.\textsuperscript{50}

Skin care products that support healthy skin are cost-effective in the prevention of skin breakdown.\textsuperscript{47,48}

New wound care treatments have the potential to significantly reduce costs for the treatment of complex and chronic wounds, and to yield even greater savings in the prevention of wound recurrence. The use of modern approaches has been more rapidly adopted by private insurers, who tend to track cost on a comprehensive basis across the full care continuum. They have consequently been able to see the economic advantages of their use. Medicare is often concerned with unit cost and tracks cost per episode for a particular site of care and, therefore, does not evaluate the full cost of caring for people with complex wounds.
VI. Medicare Policy Issues

Medicare’s cost cutting over the years has resulted in policies regarding wounds that can disrupt appropriate care delivery across clinical settings. Providers are often encumbered and/or underpaid for the use of best-practice wound care. Policies have made continuation of therapy across care settings sometimes difficult and encourage the use of less effective and ultimately more costly care approaches.

Medicare coverage policies and payment levels for newer wound treatment modalities are inconsistent, vary by clinical setting and in some cases provide no coverage at all.

For a healthy individual with a simple wound, the use of a traditional gauze-like dressing to protect and cover a wound until it heals is appropriate care. However, valuable resources are wasted when providers continue to attempt to heal complex and chronic wounds with traditional gauze-based methods, which often prolong treatment and in some cases halt the healing process altogether.

Complex and chronic wounds require advanced wound care approaches to promote healing. The first step is providing a moist-wound healing environment to maximize the wound healing response. When healing fails to progress with moist-wound healing alone, then the addition of advanced therapies and devices is essential to achieve the most rapid closure of a wound with the least complications. These approaches provide the most cost-effective care.

Decisions regarding coverage and reimbursement for moist wound healing, advanced therapies, and support surfaces have been made without consideration of the full potential cost savings and benefits to patients. As a result, inconsistent coverage and non-coverage of some advanced therapies occurs in many clinical settings.
VII. Medicare Policy Gaps

Over the last few years, Medicare has transitioned to all-inclusive Prospective Payment Systems (PPS) for a majority of the care settings in which most chronic and complex wounds are treated. This change has resulted in the incorporation of the cost of supplies and devices used for wound care in the payment structures.

Unfortunately, wounds are not uniform. They can vary based on: the patient’s current medical condition; cause of the wound; size, depth and location; presence of dead tissue and/or infection and involvement of bone or tendon damage. These differences significantly affect treatment costs. It is impossible to factor in a “set” rate for supplies and devices into any prospective payment system to cover the full spectrum of wound variation. However, this is the challenge that providers face today. Often they are forced to choose between providing care they can afford in the short term and that which would be cost-effective in the long term.

Nursing Homes/Skilled Nursing Facilities Issues

Medicare monitors nursing homes to ensure quality care is delivered to patients. The prevalence of pressure ulcers in facilities is one quality standard measured. State surveyors monitor pressure ulcer data and identify facilities which are outside the average rate. If a facility appears to have higher than average rates of pressure ulcers, an inspection is initiated to determine the cause. If a pressure ulcer is determined to have been “avoidable,” the facility may be fined. The failure to recognize and prevent the development of pressure ulcers is assigned a “deficiency level.” Depending on the level of harm to the patient, the facility would be charged penalties for failure to prevent the ulcer. Recently Medicare increased the deficiency level and associated financial penalties for the existence of even a beginning stage ulcer.

1. Inadequate payment to manage and prevent pressure ulcers.

Medicare pays nursing home providers an all-inclusive rate for “skilled” care in facilities. The rate is based on a classification group, or Resource Utilization Group (RUG). Payments are meant to be calculated according to the severity of the patient’s conditions. However, the system is flawed. A patient may have two major conditions, such as a stoke that requires rehabilitative services and a wound. However, only one RUG category will be assigned, usually based on the patient’s most severe or resource-demanding condition. As a result, the facility payment would only reflect the primary condition. There is no additional payment for a secondary condition such as a wound. The facility is therefore required to provide care without adequate reimbursement for the wound.

Supplies (including wound dressings) are included in the PPS payment to the facility. A set amount for supplies is applied to each RUG category regardless of need or utilization. This results in severe underpayment for supplies needed for complex wound care. Preventive skin care products, cleansers and protective dressing also must be provided from the facility payment rate. As a result, Medicare encourages the use of the “least expensive” product to provide care instead of the best product to provide optimal healing.

There is an ‘disconnect’ between the requirement to prevent pressure ulcers and coverage for technologies that could help achieve that goal. Providers are penalized for the development of pressure ulcers, yet Medicare does not pay facilities for preventive skin care products, protective dressings or support surfaces that relieve pressure and therefore reduce incidence. Facilities are effectively under-paid for using adequate preventive measures.

2. Advanced Therapies not included in the overall payment to the provider.

Support surfaces used for reducing pressure for existing pressure ulcers and preventing development in high-risk patients are not paid for in addition to the daily care rate. In addition, advanced devices such as negative pressure wound therapy (NPWT) and electrical stimulation therapy are not included in payment calculations. Therefore, use of these modalities to improve healing comes out of the
facility payment rate. NPWT, Low energy non-
contact ultrasound, off-loading devices and support
surfaces are considered to be Durable Medical
Equipment (DME), which are not covered items in
this setting.

Tissue/skin replacements and growth factor therapy
also are not covered, yet many of the wounds treated
in nursing facilities would benefit from their use.

3. All wound types are not accounted for
in the assessment document.

Even if the wound is the primary diagnosis, the
Minimum Data Set (MDS) assessment document
used to determine the patient’s medical needs does
not take into account all wound types. For example,
chronic diabetic foot ulcers and arterial ulcers are not
identified.

Physician Office Issues

Inadequate payment for moist-wound
healing dressings and compression
therapy.

In the physician’s office, the application of a moist-
wound healing dressings and sustained moderate-
high compression therapy is not reimbursed
adequately. The data used to calculate the physician
office fees for Medicare payments, which include
supplies, are not calculated on the assumption that
modern moist-wound healing products or advanced
compression therapy will be used. The cost for
supplies that is built into the physician payment fee is
based on simple “Band-aid” type covers or gauze
patch-type dressings. Ultimately physicians are
penalized if they try to provide “best practice” moist-
wound healing and compression therapy in their
office.

Out-Patient Clinic Issues

Inadequate payment for moist-wound
healing dressings and compression
therapy.

Medicare provides coverage and payment in the out-
patient clinic setting under a PPS model. Procedures
and clinic visits are identified under APC
(Ambulatory Payment Classification) codes with a
corresponding fee. Supplies are included in these
rates, but the supply calculations in APCs are
inadequate to cover moist-wound healing dressings
and compression therapy. There is currently no
mechanism to account for the use and cost of these
products in a clinic. Unfortunately, moist-wound
healing dressings and compression therapy generally
are the most appropriate management option for
many wounds seen in a clinic setting. Essentially,
the clinic is under-reimbursed if the clinician
provides “best practice” care.

Some, but not all, advanced therapies and devices are
covered in addition to the clinic payment, if they
qualify for a “pass-through” code. However, this is a
temporary measure for 2-3 years until the device or
therapy is rolled into the overall payment system and
has historically resulted in reduced payment.

Home Health Services

Patients receiving Medicare home health service
have greater access to some advanced therapies than
in other care settings because of appropriate payment
for wound-healing devices. This is not the case for
moist-wound healing and adjunctive therapies.

1. Coverage policy for support surfaces
used in the home may force a treatment
change from that recommended by the
hospital at the time of discharge.

Support surfaces may not be covered as a
continuation of treatment initiated in a hospital, so in
some cases the patient has a change in their treatment
care plan at home, even if that change was not
clinically indicated at the time of discharge.

2. Inadequate payment for moist-wound
healing dressings and compression
therapy.

Medicare pays a home health agency, based on the
needs of the patient, according to classification
groups, known as Home Health Resource Groups
(HHRG). Wound dressings and compression
supplies are included in the HHRG payment. A flat
amount is applied to each HHRG for supplies,
regardless of need or utilization. This often results in
significant underpayment for wound care
management.
3. Wounds covered with dead tissue are initially not calculated in payment rates.

The OASIS assessment document used to define the condition and needs of home health care patients is flawed with respect to wound care provisions. A wound covered with dead tissue can not be assessed until the tissue is removed. As a result, there is no mechanism to calculate, or pay for, the care and removal of the dead tissue – an often costly process that can take days or weeks. However, if the patient were in a nursing home instead, the Medicare PPS would calculate payment for care of the same type wound from the beginning.

Patients at Home Not Receiving Home Health Care or Residing in Long Term Care Facilities (Nursing Homes)

The Medicare Part B Surgical Dressing Policy provides coverage for wound dressings for patients in the home or Long Term Care facilities.

1. Medicare Part B does not cover all chronic wounds.

The Medicare Part B Surgical Dressing Policy only allows coverage and reimbursement of dressings if the wound is a surgical wound or if the wound has had dead tissue removed. This policy eliminates coverage for many chronic wounds.

2. Medicare Part B does not cover wound dressings for early pressure ulcers.

An early Stage I pressure ulcer, which is the first sign of tissue breakdown and the least difficult wound to heal, is not covered under this policy.

3. Medicare Part B has no dressing category for antimicrobial dressings.

Controlling the risk of infection is a critical factor in preventing wound deterioration, life-threatening conditions and/or loss of limb. Moist-wound healing dressings with added antimicrobial features, such as silver, are now available. However, Medicare policy does not adequately recognize or reimburse for antimicrobial dressing use.

4. Medicare Part B has restrictions on the use of some dressing types that do not match current clinical practice

A common clinical practice to manage draining wounds is to use a combination of dressing types to better manage the wound and prolong times between dressing changes. Some of the current guidelines in the policy prohibit using some dressing combinations. Hence, the policy does not align with “best” clinical practice that incorporates less frequent dressing changes which promotes faster healing, lessens the risk of infection and uses fewer resources.

5. Medicare Part B does not cover wound prevention.

The current Medicare B Surgical Dressing Policy lacks coverage for dressings or skin care products to reduce damage and prevent wounds from developing. For example, Medicare has no policy for reduction of recurrence of venous ulcers with compression therapy.
<table>
<thead>
<tr>
<th></th>
<th>Hospital</th>
<th>Physician Office</th>
<th>Out-Pt. Clinic</th>
<th>Home Health Services</th>
<th>Skilled Nursing Facility &amp; LTC</th>
<th>At Home</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Moist-healing dressings:</strong></td>
<td>gauze only</td>
<td>gauze only</td>
<td>gauze only</td>
<td>Flat fee – not based on use</td>
<td>Part A - flat fee not based on use</td>
<td>Part B</td>
</tr>
<tr>
<td><strong>NPWT</strong></td>
<td>not covered</td>
<td>not covered</td>
<td>not covered</td>
<td>covered</td>
<td>Part A - no Part B – no</td>
<td>not covered w/o Home Health services</td>
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<tr>
<td><strong>Skin/Tissue Replacements</strong></td>
<td>not covered</td>
<td>covered</td>
<td>covered</td>
<td>not covered</td>
<td>Part A - no</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>E-Stimulation</strong></td>
<td>not covered</td>
<td>covered</td>
<td>covered as therapy</td>
<td>covered as therapy</td>
<td>Part A – no Part B as therapy</td>
<td>not covered w/o Home Health services</td>
</tr>
<tr>
<td><strong>Low energy non-contact ultrasound</strong></td>
<td>Not covered</td>
<td>Not covered</td>
<td>Not covered</td>
<td>Not covered</td>
<td>Not covered</td>
<td>Not covered</td>
</tr>
<tr>
<td><strong>HBOT</strong></td>
<td>not covered</td>
<td>not covered</td>
<td>covered as therapy</td>
<td>N/A</td>
<td>Part B as therapy</td>
<td>N/A</td>
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<tr>
<td><strong>PDGF</strong></td>
<td>not covered</td>
<td>not covered</td>
<td>not covered</td>
<td>not covered</td>
<td>Part A - no</td>
<td>not covered</td>
</tr>
<tr>
<td><strong>Autologous GF therapy</strong></td>
<td>not covered</td>
<td>not covered</td>
<td>not covered</td>
<td>not covered</td>
<td>Part A – no</td>
<td>not covered w/o Home Health services</td>
</tr>
<tr>
<td><strong>SGMHC</strong></td>
<td>not covered</td>
<td>not covered</td>
<td>not covered</td>
<td>Not covered</td>
<td>Part A – no Part B- only debrided VU</td>
<td>Part B. No coverage to prevent VU</td>
</tr>
<tr>
<td><strong>Support Surfaces</strong></td>
<td>not covered</td>
<td>N/A</td>
<td>N/A</td>
<td>Part B covered</td>
<td>Part A – no Part B – no</td>
<td>Part B</td>
</tr>
<tr>
<td><strong>Off-loading devices, walking boots</strong></td>
<td>not covered</td>
<td>N/A</td>
<td>Part B w/ restrictions by condition</td>
<td>Part B w/ restrictions by condition</td>
<td>Part A- no Part B – custom only</td>
<td>Part B No use for PU or DU prevention</td>
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<tr>
<td><strong>Skin Protection</strong></td>
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<td>not covered</td>
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<td>not covered</td>
<td>not covered</td>
<td>not covered</td>
</tr>
</tbody>
</table>

NPWT – Negative Pressure Wound Therapy
PDGF - Platelet Derived Growth Factor
SGHMC - sustained, graduated, high – moderate compression
HBOT - Hyperbaric Oxygen Therapy

VU - Venous Ulcer
DU - Diabetic Ulcer
PU – Pressure Ulcer
Incorporating “best practice” care for the management of complex and chronic wounds is essential for more efficient and effective wound healing. Chronic and complex wounds are difficult to heal, take a long time to heal and can lead to serious complications including amputation and death. Most chronic wounds are the result of underlying medical conditions. Correction and/or management of those conditions along with treatment of the wound itself require considerable resources.

Chronic and complex wounds greatly impact patients, the healthcare system and the U.S. economy overall:

- Complications from pressure ulcers kill 60,000 people per year, twice the number who die from prostate cancer.15
- 15% of people with diabetes will develop an ulcer at some time during their lifetime;
- 1% of all people over 60 have a leg ulcer;
- Hospital stays for people who have a primary diagnosis of pressure ulcer are five times longer hospital stay than people without an ulcer.30
- Diabetic foot ulcers and associated complications lead to over 82,000 amputations annually
- The direct and indirect costs of such lower extremity amputations can range from $20,000-60,000.27
- Venous leg ulcers account for the loss of two million workdays a year

New technologies are being developed at an ever faster rate, but approval for their coverage and reimbursement and their inclusion in policies lags far behind. In wound management, inconsistent and inadequate coverage for “best practice” and advance therapies across all care settings makes it more difficult for clinicians to provide highest quality care. As a result, patients often do not receive coherent, cost-effective treatment.

Dr. Mark McClellan, Administrator of the Centers for Medicare and Medicaid Services (CMS), has recognized there are gaps in Medicare policy that will need to be adjusted to provide care that is in line with modern medical approaches. In July 2004, Dr. McClellan observed: “too many beneficiaries haven’t used services that make it possible to detect and treat illnesses before they lead to serious health problems and avoidable health care costs.” He added, “in recent years, Medicare benefits fell behind modern medicine, especially when it comes to prescription drugs, preventive care, and more affordable health plan options.”

Prevention and early, appropriate treatment is critical to meeting the government initiative to reduce pressure ulcers in nursing facilities to below 1% by 2010. Revisions are needed to the coverage and reimbursement mechanisms for physician offices, nursing facilities, out-patient clinics and home health services to encourage the use of moist-wound healing and advanced wound care techniques.
AdvaMed Recommendations

To encourage adoption of cost-effective wound-healing approaches for chronic and complex wound management, the following recommendations need to be considered:

1. Increase the wound care supply allocation in the Medicare prospective payment systems (PPS) for skilled nursing facilities, home health services and out-patient clinics to encourage the appropriate use of advanced technologies, including moist-wound healing dressings for wound management.
2. Revise the PPS for skilled nursing facilities to reflect the incremental cost for the necessary treatment and therapy of a wound when it is not the primary diagnosis.
3. Allow physicians to bill for wound dressings and compression therapy supplies, using HCPCS codes, when providing services in the office.
4. Provide coverage for wound-related Durable Medical Equipment (DME) in nursing facilities, including support surfaces, off-loading devices and vacuum assisted-closure for prevention and treatment of chronic wounds.
5. Provide coverage within the Part B Surgical Dressing Benefit for preventive and early intervention technologies for tissue damage.
6. Update the Surgical Dressing Policy’s categories and associated fees – currently based on product composition and/or structure – to reflect the performance of the dressing.
7. Include a new category in the Surgical Dressing Policy for dressings that contain an active antimicrobial agent, such as silver.
8. Revise the MDS and OASIS assessment documents to: correctly identify all wound types, consistently stage and assess pressure ulcers, consistently account for management and treatment and adequately reimburse for care. Revisions should also direct the clinician to appropriate documentation necessary to support the medical necessity of DME products.
9. Wound dressings and support surfaces should not be included in the DMEPOS Competitive Acquisition Program. Access to these products must be broad and open enough to encourage their use to heal wounds more quickly, with fewer complications and less overall cost to the health care system.
10. Provide Medicare coverage of compression technologies for healed venous ulcers to reduce recurrence rates and reduce overall treatment costs.
11. Expand coverage policies for advanced therapies such as Negative Pressure Wound Therapy, low energy non-contact ultrasound, off-loading devices and support surfaces to encourage consistent treatment planning as the patient moves through the health care system.
12. Support a more aggressive approach to the treatment of chronic wounds which allows for the appropriate therapies to be used earlier in the treatment plan to control overall cost of wound care, rather than have treatment plans designed to reduce price by line item.
References:

42. American Medical Directors Association: Pressure Ulcer Therapy Comparisons, 1999.
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Page 8: Venous ulcer: ConvaTec, A Bristol-Myers Squibb Company
Page 9: Diabetic foot wound bottom of foot, amputation of toe, wound with black eschar, infected wound: ConvaTec, A Bristol-Myers Squibb Company
Page 12: Gauze removed from wound: ConvaTec, A Bristol-Myers Squibb Company
Page 15: Heel ulcer pictures: ConvaTec, A Bristol-Myers Squibb Company

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