

**Physician-Focused Payment Model Technical Advisory Committee
LOI: Environmental Scan & Relevant Literature**

**BenchMark Rehab Partners
Letter Dated: 9/20/2017
Letter Received: 9/21/2017**

BenchMark Rehab Partners (BMRP) is an outpatient physical rehabilitation provider operating 300+ private outpatient clinics across 13 states. BMRP is proposing a payment model called CMS Support of Wound Care in Private Outpatient Therapy Clinics that lowers cost of care while providing chronic wound care services to Medicare beneficiaries.

The model will demonstrate the cost savings of using physical and occupational therapists in private outpatient settings compared to traditional outpatient hospital-based wound care centers. BenchMark aims to serve as a pilot institution for measuring the effectiveness of physical or occupational therapy intervention to manage wounds in Medicare recipients by tracking the patients' functional outcomes, total cost of treatment, and total time in treatment in 20 facilities nationwide, in geographically dispersed areas. This model proposes to treat and track patients by eliminating the Medicare cap and threshold exceptions, implementing a one-time reimbursable charge of \$250 per patient for wound care supplies, and allowing for the use and billing of the low cost skin substitutes and bioengineered dressings for patients. BMRP intends for this payment model to help demonstrate the effectiveness of physical and occupational therapy in the healing of chronic wounds, demonstrate the overall increase in functional outcomes experienced by patients with chronic wounds who are being primarily managed by physical and occupational therapists, and demonstrate the cost savings of utilizing physical and occupational therapists in outpatient, private settings versus traditional outpatient hospital-based wound care centers.

BenchMark's expected participants include 200 physicians, 10 physicians from each of the 20 wound treatment location.

Key Search Terms

Active wound healing; Chronic wound care services; Cost; Hospital outpatient; Intervention; MACRA; Medicare; Medicare cap; Occupational therapy; Payment model; Physical therapy; Private outpatient; Reimbursement; Traditional hospital-based; Wound care

Research Task	Section	Contents
Environmental Scan	Section 1	Key documents, timely reports, grey literature, and other materials gathered from internet searches (7).
Relevant Literature	Section 2	Relevant literature materials (3).
Related Literature	Section 3	Related literature materials (2).

Section 1. Environmental Scan

Environmental Scan		
<i>Key words: Cap; MACRA; Physical Therapy</i>		
Organization	Title	Date
Centers for Medicare & Medicaid Services (CMS)	Therapy Services	Accessed on: 9/26/2017 Last Modified: 9/19/2017
Purpose/Abstract		
<p>Background: Physical and occupational therapists will use a total of eight new CPT codes to bill Medicare for evaluations and re-evaluations.</p> <p>Summary: Beginning January 1, 2017, existing physical therapy (PT) and occupational (OT) evaluation codes will be replaced with three new codes, representing low, moderate or high complexity. The re-evaluation codes will also be replaced. The new CPT codes represent “always therapy” services and require the corresponding discipline-specific therapy modifier: (a) the new PT codes (97161 – 97164) require the “GP” modifier, and (b) the new OT codes (97165 – 97168) require the “GO” modifier. Under Medicare Part B, “therapy caps” commonly refer to the annual limitations on per beneficiary incurred expensive for OT services. For CY 2017, the limit for combined physical therapy and speech-language pathology services is \$1,980, and the limit for occupational therapy services is \$1,980.</p>		
Additional Notes/Comments		
<p>For more information about the therapy caps and other therapy payment policies, please see:</p> <ul style="list-style-type: none"> • The Medicare Claims Processing Manual, Chapter 5. • For applicable coverage policies for therapy services, please refer to the Medicare Benefits Policy Manuals: <ul style="list-style-type: none"> ○ Sections 220 and 230 of Chapter 15, and Chapter 12 for PT, OT, and SLP services in Comprehensive Outpatient Rehabilitation Facilities 		

Environmental Scan		
<i>Key words: Chronic wound care; CMS; Healing; Payment model; Reimbursement</i>		
Journal	Title	Date
Today's Wound Clinic	Wound Care Reimbursement in 2017: Manufacturers & Management Companies Speak Out	3/3/2017
Purpose/Abstract		
<p>Background: Several manufacturers and management companies in the United States shared information on how their business models are adapting to the volume-driven and value-driven reimbursement system for wound care.</p> <p>Summary: Alliqua Biomedical, Comprehensive Healthcare Solutions Inc., Integra Life Sciences, and ManukaMed discuss success and limitations within their models.</p> <ul style="list-style-type: none"> • Alliqua Biomedical states that while their products are clinically proven to produce effective and efficient results, their best clinical outcomes are not cost-effective. There is a lack of published coverage policies. They state the biggest challenge with Medicare is the hospital outpatient department packaging of payments into the primary service. • Comprehensive Healthcare Solutions Inc. has assisted in development of wound and/or hyperbaric programs in hospitals nationwide. Comprehensive offers customization and alternative options to produce cost-effective wound care service that helps reduce readmissions and length of hospital stays. • Integra LifeSciences states the current fee-for-service (FFS) model provides financial incentives to encourage practitioners to deliver more services to increase the reimbursement they receive. However, an FFS healthcare system is not cost-efficient to healing chronic wounds since wound care requires multiple visits from the patient. Under a healthcare system moving towards a value-based structure, practitioners are paid in the services they deliver, and are rewarded or penalized for patient outcomes. Integra's advanced cellular and tissue-based products have shortened healing times compared to standard therapies, and are customized to differently sized wounds to reduce waste. The reduced number of applications leads to direct cost savings on the products and total cost of the care, which ultimately results in increasing access of care to patients and lowering overall cost of care to the healthcare system. • ManukaMed is a small wound care company who faced challenges with the CMS Pricing, Data Analysis and Coding (PDAC) ruling made in August 2015. The company was able to manufacture a product that met CMS specifications, called MEDSAF, that can be included in the Medicare B options as fixed-fee-coded dressings covered by CMS. 		
Additional Notes/Comments		

Environmental Scan		
<i>Key words: physical therapy; wound management</i>		
Journal	Title	Date
Academy of Clinical Electrophysiology & Wound Management (ACEWM)	The Role of Physical Therapists in Wound Management	1/2017
Purpose/Abstract		
<p>Background: The Academy of Clinical Electrophysiology and Wound Management’s (ACEWM) Wound Management Special Interest Group’s (WMSIG) vision for the future is that physical therapists (PTs) will be recognized as vital members of the multidisciplinary wound management team.</p> <p>Summary: This white paper describes the role of physical therapists in wound management through discussion of contemporary entry-level education, intervention, state-specific considerations, and involvement across practice settings, and reimbursement issues. The paper states ways in which a physical therapist can contribute to a wound care team. It discusses the extensive knowledge required of entry-level and post-professional PTs on wound management as well as provides a list of several exercise interventions to enhance healing and improve functional outcome. PT involvement in wound management varies by state, since there is clearly defined text regarding PT practice for each state. PT involvement ranges from acute care, outpatient, and skilled nursing practice settings. The paper also discusses strategies to help establish a structure for reimbursing PTs in wound management around coverage, coding, and payment.</p>		
Additional Notes/Comments		

Environmental Scan		
<i>Key words: Code; Billing; Medicare; Wound care</i>		
Organization	Title	Date
Centers for Medicare & Medicaid Services (CMS)	Billing and Coding Guidelines for Wound Care	1/1/2017
Purpose/Abstract		
<p>Background: The Centers for Medicare & Medicaid Services (CMS) provides billing and coding guidelines for wound care.</p> <p>Summary: The document provides 13 billing guidelines (CPT Codes 97597, 97598 and 11042-11047) and four coding guidelines. Additionally, the guidelines also indicate two reasons for denial: 1) performing deep debridement in POS other than inpatient hospital, outpatient hospital or ASC and 2) billing of debridement by unqualified personal.</p>		
Additional Notes/Comments		
<p>American Physical Therapy Association (APTA) provides summaries, fact sheets, comments, and additional resources on the Medicare physician fee schedule for billing and coding for CY 2011-2017: http://www.apta.org/Payment/Medicare/CodingBilling/FeeSchedule/</p>		

Environmental Scan		
<i>Key words: Medicare; Outpatient therapy</i>		
Organization	Title	Date
Noridian Healthcare Solutions, LLC	Outpatient Therapy Services	2017
Purpose/Abstract		
<p>Background: The Part B Provider Outreach and Education (POE) Advisory Group assisted Noridian in presenting materials related to Outpatient Therapy Services for Medicare beneficiaries.</p> <p>Summary: The presentation provides a background on Outpatient Therapy Services relating to Medicare. It highlighted general therapy guidelines, information on Therapy Cap and its exception, evaluation of new codes, advance beneficiary notice, documentation, and additional Medicare information. More detailed Information can be found via links provided within the presentation.</p>		
Additional Notes/Comments		

Environmental Scan		
<i>Key words: Medicare; Wound care</i>		
Journal	Title	Date
Advances in Wound Care	Medicare Payment: Surgical Dressings and Topical Wound Care Products	8/1/2014
Purpose/Abstract		
<p>Background: The author reviews the Medicare payment systems in acute care hospitals, long-term acute care hospitals, skilled nursing facilities, home health agencies, durable medical equipment suppliers, hospital-based outpatient wound care departments, and qualified healthcare professional offices.</p> <p>Summary: According to numerous wound care management companies, Medicare is the largest third-party payer for patients with chronic wounds. The Medicare payment system greatly influences the patients' access to surgical dressings and topical wound care products. Qualified healthcare professionals should consider these payment systems, as well as the medical necessity for surgical dressings and topical wound care products. Scientists and manufacturers should also consider these payment systems, in addition to the Food and Drug Administration (FDA) requirements for clearance or approval, when they are developing new surgical dressings and topical wound care products. Specifically under the Outpatient Prospective Payment Systems (OPPS) resource-based Medicare payment system hospital-based outpatient wound care departments (HOPD), the departments receive payment for the services, procedures, and/or separately payable drugs and biologicals provided to the patients at each visit. Biologicals, such as cellular and/or tissue-based products for wounds, are separately payable to the HOPDs if they are assigned a separately payable HCPCS code, if the patient has Medicare Part B coverage, and if the products are covered by the Medicare Administrative Contractor (MAC). Medicare considers negative pressure wound therapy pumps and supplies as durable medical equipment by Medicare, thus the HOPDs are not required to supply the equipment, canisters, dressings etc. Instead, the patients acquire those items from their durable medical equipment supplier. However, the qualified wound care professionals, who write the order for the negative pressure wound therapy pumps, must follow the guidelines of the Medicare LCD for Negative Pressure Wound Therapy Pumps. The HOPDs can bill for the work of applying the negative pressure wound therapy pump and dressings, as long as a surgical procedure (such as debridement of subcutaneous tissues) is not performed at the same encounter.</p>		
Additional Notes/Comments		

Environmental Scan		
<i>Key words: Medicare; Private outpatient; Wound care</i>		
Organization	Title	Date
Centers for Medicare & Medicaid Services (CMS)	Developing Outpatient Therapy Payment Alternatives (DOTPA)	1/2013
Purpose/Abstract		
<p>Background: Outpatient therapy services, composed of physical therapy, occupational therapy, and speech-language pathology, are covered by Part B of the Medicare program. The report provides descriptive information about the use and expenditure for outpatient therapy services in CY 2010.</p> <p>Summary: The overall results in CY 2010 for Outpatient Therapy Utilization are as follows: a total of 4,697,349 individuals received physical therapy (PT), occupational therapy (OT), and/or speech-language pathology (SLP) services. This number represents 13.5 percent of the 34,682,126 FFS beneficiaries¹¹ enrolled in Part B, and a 1.4% increase from the total number of outpatient therapy users in CY 2009. PT had the most users at 4,156,895 (89.0 percent), followed by OT with 1,043,011 users (22.0 percent), and SLP with 526,628 users (11.0 percent). Note that the sum of users of PT, OT, and SLP services is greater than the total number of users because some patients receive therapy from multiple disciplines. Of the 4,697,349 beneficiaries who received therapy services under Medicare Part B in CY 2010, a total of 971,716 (20.7 percent) reached or exceeded at least one of the two therapy caps. Of those receiving OT, 236,148 (22.6 percent) exceeded the OT therapy cap; among those receiving either PT or SLP, 902,188 (20.5 percent) reached or exceeded the PT/SLP cap.</p>		
Additional Notes/Comments		

Section 2. Relevant Literature

Relevant Literature		
<i>Key words: Chronic wound care; Medicare</i>		
Journal	Title	Date
Value in Health	An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds	9/19/2017
Purpose/Abstract		
<p>Objective: The aim of this study was to determine the cost of chronic wound care for Medicare beneficiaries in aggregate, by wound type and by setting.</p> <p>Methods: This retrospective analysis of the Medicare 5% Limited Data Set for calendar year 2014 included beneficiaries who experienced episodes of care for one or more of the following: arterial ulcers, chronic ulcers, diabetic foot ulcers, diabetic infections, pressure ulcers, skin disorders, skin infections, surgical wounds, surgical infections, traumatic wounds, venous ulcers, or venous infections. The main outcomes were the prevalence of each wound type, Medicare expenditure for each wound type and aggregate, and expenditure by type of service.</p> <p>Results: Nearly 15% of Medicare beneficiaries (8.2 million) had at least one type of wound or infection (not pneumonia). Surgical infections were the largest prevalence category (4.0%), followed by diabetic infections (3.4%). Total Medicare spending estimates for all wound types ranged from \$28.1 to \$96.8 billion. Including infection costs, the most expensive estimates were for surgical wounds (\$11.7, \$13.1, and \$38.3 billion), followed by diabetic foot ulcers (\$6.2, \$6.9, and \$18.7 billion,). The highest cost estimates in regard to site of service were for hospital outpatients (\$9.9–\$35.8 billion), followed by hospital inpatients (\$5.0–\$24.3 billion).</p> <p>Conclusions: Medicare expenditures related to wound care are far greater than previously recognized, with care occurring largely in outpatient settings. The data could be used to develop more appropriate quality measures and reimbursement models, which are needed for better health outcomes and smarter spending for this growing population.</p>		
Additional Notes/Comments		

Relevant Literature		
Key words: Physical therapy; Wound care		
Journal	Title	Date
Medicine (Wolters Kluwer)	Physical Therapy in Wound Care	12/2015
Purpose/Abstract		
<p>Background: Management of chronic wounds remains unsatisfactory in terms of treatment cost and time required for complete wound closure (CWC). This study aimed to calculate the healing rates, estimated cost, and time required for CWC in wounds; compare estimated wound care costs between healing and nonhealing wounds; and compare cost effectiveness between venous leg ulcer (VLU) and non-VLU.</p> <p>Methods: This was a retrospective cohort study performed at a physical therapy (PT) wound care clinic. Deidentified patient data in the electronic medical database from September 10, 2012 to January 23, 2015 were extracted.</p> <p>Results: Among 159 included patients with wounds, 119 (74.84%) patients were healed with CWC. The included patients were treated for 109.70±95.70 days, 29.71±25.66 visits, and at the costs per treatment episode of \$1629.65±1378.82 per reimbursement rate and \$2711.42±2356.81 per breakeven rate. For patients with CWC (healing group), the treatment duration was 98.01±76.12 days with the time for CWC as 72.45±64.21 days; the cost per treatment episode was \$1327.24±1143.53 for reimbursement rate and \$2492.58±2106.88 for breakeven cost. For patients with nonhealing wounds, treatment duration was found to be longer with costs significantly higher ($P<0.01$ for all). In the healing group, no differences were found between VLU and non-VLU in treatment duration (95.46 days vs. 100.88 days, $P=0.698$), time for CWC (68.06 days vs. 77.38 days, $P=0.431$), and cost (\$2756.78 vs. 2397.84 for breakeven rate, $P=0.640$) with the exception of wound dressing costs (\$329.19 vs. 146.47, $P=0.001$).</p> <p>Limitations: Healing rates may be affected with patient exclusions. Costs at physicians' offices were not included.</p> <p>Conclusion: Incorporation of PT in wound care appeared to be cost effective. PT may thus be a good referral option for patients with wounds. However, the results should be interpreted cautiously and further studies are warranted.</p>		
Additional Notes/Comments		

Relevant Literature		
Key words: Cost; Chronic wound care; Intervention		
Journal	Title	Date
Applied Health Economics and Health Policy	Economic Evaluations of Guideline-Based or Strategic Interventions for the Prevention or Treatment of Chronic Wounds	3/11/2014
Purpose/Abstract		
<p>Background: Costs of chronic wound care are significant, but systematic reviews of cost-effectiveness studies regarding guideline-based or strategic interventions are scarce.</p> <p>Objectives: The objectives were to assess/compare the cost effectiveness of new interventions/systems designed to improve the prevention/treatment of chronic wounds in adult populations against current care and provide decision makers with information on which to base future interventions for chronic wound management.</p> <p>Study Eligibility Criteria, Participants, and Interventions: The authors included comparative health economic evaluations of interventions published in English designed to prevent or treat adult chronic wounds that were guideline-based or strategic in nature and from which an incremental cost-effectiveness ratio or incremental net health benefit was reported or could be calculated.</p> <p>Study Appraisal and Synthesis Methods: Study and model characteristics and outcomes were extracted into pre-designed tables. Quality assessment of studies was based on literature-reported methods. Studies were assigned strength of evidence ratings and recommendation level for decision makers.</p> <p>Results: A total of 16 health economic evaluations were included, of which ten were trial based and six were wholly model based. Only three studies had high, and five studies moderate, strength of evidence and were recommended for decision makers. All studies had some shortcomings regarding time horizon, costs, effectiveness units, and methodological reporting. Two studies had major flaws.</p> <p>Conclusions and Implications of Key Findings: Few well conducted cost-effectiveness studies exist to guide decision makers regarding guideline-based or strategic interventions for chronic wounds.</p>		
Additional Notes/Comments		

Section 3. Related Literature

Related Literature		
<i>Key words: Medicare; Occupational therapy; Payment; Physical therapy</i>		
Journal	Title	Date
Physical Therapy	Refinements of the Medicare Outpatient Therapy Annual Expenditure Limit Policy	6/18/2015
Purpose/Abstract		
<p>Background: A Medicare beneficiary's annual outpatient therapy expenditures that exceed congressionally established caps are subject to extra documentation and review requirements. In 2011, these caps were \$1,870 for physical therapy and speech-language pathology combined and \$1,870 for occupational therapy separately.</p> <p>Objective: This article considers the distributional effects of replacing current cap policy with equal caps by therapy discipline (physical therapy, occupational therapy, and speech-language pathology) or a single combined cap, and risk adjusting the physical therapy cap using beneficiary characteristics and functional status.</p> <p>Methods: Alternative therapy cap policies are simulated with 100% Medicare claims for 2011 therapy users (N=4.9 million). A risk-adjusted cap for annual physical therapy expenditures is calculated from a quantile regression estimated on a sample of physical therapy users with diagnoses and clinician assessments of functional ability merged to their claims (n=4,210).</p> <p>Results: Equal discipline-specific caps of \$1,710 each for physical therapy, occupational therapy, and speech-language pathology result in the same aggregate Medicare expenditures above the caps as 2011 cap policy. A single combined-disciplines cap of \$2,485 also results in the same aggregate expenditures above the cap. Risk adjustment varies the physical therapy cap by as much as 5 to 1 across beneficiaries and equalizes the probability of exceeding the physical therapy cap across diagnosis and functional status groups.</p> <p>Limitations: One limitation of the study was the assumption of no behavioral response on the part of beneficiaries or providers to a change in cap policy. Additionally, analysis of risk adjusting the therapy caps was limited by sample size.</p> <p>Conclusions: Equal discipline-specific caps for physical therapy, occupational therapy, and speech-language pathology are more equitable to high users of both physical therapy and speech-language pathology than current cap policy. Separating the physical therapy and speech-language pathology caps is a change that policy makers could consider. Risk adjustment of the therapy caps is a first step in incorporating beneficiary need for services into Medicare outpatient therapy payment policy.</p>		
Additional Notes/Comments		

Related Literature		
Key words: CMS; Cost; Medicare; Physical therapy		
Journal	Title	Date
The Journal of Bone and Joint Surgery	Associations Between Preoperative Physical Therapy and Post-Acute Care Utilization Patterns and Cost in Total Joint Replacement	10/1/2014
Purpose/Abstract		
<p>Background: Health-care costs following acute hospital care have been identified as a major contributor to regional variation in Medicare spending. This study investigated the associations of preoperative physical therapy and post-acute care resource use and its effect on the total cost of care during primary hip or knee arthroplasty.</p> <p>Methods: Historical claims data were analyzed using the Centers for Medicare & Medicaid Services Limited Data Set files for Diagnosis Related Group 470. Analysis included descriptive statistics of patient demographic characteristics, comorbidities, procedures, and post-acute care utilization patterns, which included skilled nursing facility, home health agency, or inpatient rehabilitation facility, during the ninety-day period after a surgical hospitalization. To evaluate the associations, we used bivariate and multivariate techniques focused on post-acute care use and total episode-of-care costs.</p> <p>Results: The Limited Data Set provided 4733 index hip or knee replacement cases for analysis within the thirty-nine-county Medicare hospital referral cluster. Post-acute care utilization was a significant variable in the total cost of care for the ninety-day episode. Overall, 77.0% of patients used post-acute care services after surgery. Post-acute care utilization decreased if preoperative physical therapy was used, with only 54.2% of the preoperative physical therapy cohort using post-acute care services. However, 79.7% of the non-preoperative physical therapy cohort used post-acute care services. After adjusting for demographic characteristics and comorbidities, the use of preoperative physical therapy was associated with a significant 29% reduction in post-acute care use, including an \$871 reduction of episode payment driven largely by a reduction in payments for skilled nursing facility (\$1093), home health agency (\$527), and inpatient rehabilitation (\$172).</p> <p>Conclusions: The use of preoperative physical therapy was associated with a 29% decrease in the use of any post-acute care services. This association was sustained after adjusting for comorbidities, demographic characteristics, and procedural variables.</p> <p>Clinical Relevance: Health-care providers can use this methodology to achieve an integrative, cost-effective, patient care pathway using preoperative physical therapy.</p>		
Additional Notes/Comments		

Overview

Title: Literature review regarding the evidence behind the use and effectiveness of skin substitutes in chronic wound care

Objective/ Research Question: What is the effectiveness of skin substitutes in the care of chronic wounds?

Methods: We searched Pubmed and GoogleScholar for recent systematic reviews (within the last 5 years) and randomized trials of skin substitutes for the treatment and care of chronic wounds in older adults. Within PubMed, systematic reviews as study type were searched for studies on the use of skin substitutes using keywords skin substitutes, chronic wounds, wound care, wound care program, diabetes, ulcers.

Six systematic reviews on topic were retrieved from 2015-2018, with preference given to more recent reviews and free articles. Most reviews and RCTs evaluated the efficacy or effectiveness of single product for single wound type—these were not retrieved as more summative information was needed for this limited review.

Background

Chronic wounds have a profound effect on a patient's health and quality of life, similar to that of living with serious kidney disease and heart failure⁶. Chronic wounds are those that fail to heal by three months and result in significant morbidity and mortality, particularly among older adults⁶. Estimates indicate that 6.5 million individuals are affected per year and numbers may be growing². Chronic wound incidence increases with age, with venous ulcers occurring three to four times as frequently and pressure ulcers five to seven times as frequently in individuals aged 80 or older, even when compared to those aged 65 to 70⁶. Ninety percent of all chronic wounds stem from diabetic ulcers, venous ulcers, or decubitus ulcers⁴, with 15 percent of patients with diabetes developing at least one foot ulcer in their lifetime⁵. These conditions are expensive for both patients and the health system, with estimates ranging from \$30,000 to as high as \$50,000 a year per patient^{2,4}. These costs can amount to between \$10 billion and \$25 billion annually for the medical system, and it is likely adults aged 65 and older account for the majority of these costs^{2,6}.

Standard of Care/Skin-Substitutes

The current standard of care (SOC) for chronic wounds includes debridement, infection control, pressure relief, and compression techniques. Closure rates for diabetic ulcers, for example, range from 21-35 percent (at 12-20 weeks, respectively), with high relapse rates even when closure is initially successful⁴. Ensuring a patient's nutritional status is critical for wound healing at every age including among elder adults, and evidence is emerging that glycemic control is particularly important for rate of wound healing among patients with diabetes^{2,6}. Ulcers stemming from diabetes, for example, fail to close at a rate of 30 percent within 20 weeks⁵. Alternative and second-line care approaches include negative-pressure wound therapy, hyperbaric oxygen therapy, electrical stimulation, ultrasound, and the use of skin-substitutes⁶.

Skin-substitutes can consist of biological substances, synthetic materials, or engineered as a hybrid of both materials that allow for placement on the site of a wound^{1,2}. Skin substitutes are broadly defined as being either cellular or acellular¹. Cellular substitutes contain viable cells seeded over matrix

material, which promote healing through secretion of cytokines and growth factors, while acellular substitutes function more as scaffolds on which the patient’s natural fibroblasts and endothelial cells can synthesize new tissue¹. Both variations can be further broken down into the types of material, ranging from amniotic and placental substitutes with the widest applications, to more narrowly used bioengineered/human skin replacements⁴.

Evidence for the effectiveness of particular brands compared against SOC is more widely available than studies dedicated to the efficacy of any one type of skin substitute over another, making broad judgments about the efficacy of types of skin substitutes for types of wounds or groups of patients difficult³. Depicted in the table below are examples of results from clinical studies included in systematic reviews showing improved wound closure rates across brands when compared to control groups at 12 weeks^{1,4}:

<u>Brand</u>	<u>Wound Closure Rate</u>	<u>Control Wound Closure Rate</u>
Apligraf	51.5% - 56%	26.3% - 38%
Dermagraft	30% - 71.4%	14.3% - 18.3%
EpiFix	30%	18.3%
Grafix	62%	21%
OrCel	50%	31%
Oasis	54% - 55%	32% - 34%

Quality of the Evidence

Despite promising results, however, concerns about the quality of clinical trials of skin substitutes exist as well, with many limited by poorly defined outcomes, lack of standardization in data collection, and variation in the measurement and treatment of wounds⁶. In addition, skin-substitutes are costly though several studies indicate cost-effectiveness over a one-year period². Evidence of long-term wound closure rates and limb salvage rates are both currently lacking, thus any long-term cost-saving estimates must be considered cautiously^{2,5}. Biases have also been documented in studies of skin substitutes, partly because adequate blinding of study participants is almost impossible due to the highly visible nature of the intervention^{3,5}. Industry involvement in such studies is also a mainstay, with publication biases against negative results documented as well⁵. Finally, there is less evidence available for the effectiveness of skin-substitutes for non-diabetic ulcer wounds³.

In summary, skin-substitutes are thought to be effective when used as part of a multidisciplinary approach for managing chronic wounds that do not respond to more conservative or first-line therapies. For diabetic ulcers in particular, providing cells, soluble mediators, and matrix materials via skin substitutes can stimulate healing^{1,5}. Although skin-substitutes seem to increase the rate of healing, there is not yet enough evidence to form guidelines on their appropriate use at this time; current use is likely more dependent on availability and cost than effectiveness³. Cost-benefit analyses that use survival

analytic approaches and consider important outcomes such as rate of amputation, long-term follow-up, relapse and recurrence rates, and more comparable or homogenous measures of closure rate would help alleviate uncertainty about long-term results, effectiveness and cost-effectiveness if used broadly⁵.

References

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- 2: Han G, Ceilley R. Chronic Wound Healing: A Review of Current Management and Treatments. *Adv Ther*. 2017 Mar;34(3):599-610. ([Link](#))

- 3: Nicholas MN, Yeung J. Current Status and Future of Skin Substitutes for Chronic Wound Healing. *J Cutan Med Surg*. 2017 Jan/Feb;21(1):23-30. ([Link](#))

- 4: Pourmousa A, Gardner DJ, Johnson MB, Wong AK. An update and review of cell-based wound dressings and their integration into clinical practice. *Ann Transl Med*. 2016 Dec;4(23):457. ([Link](#))

- 5: Santema TB, Poyck PP, Ubbink DT. Systematic review and meta-analysis of skin substitutes in the treatment of diabetic foot ulcers: Highlights of a Cochrane systematic review. *Wound Repair Regen*. 2016 Jul;24(4):737-44. ([Link](#))

- 6: Gould L, Abadir P, Brem H, Carter M, Conner-Kerr T, Davidson J, DiPietro L, Falanga V, Fife C, Gardner S, Grice E, Harmon J, Hazzard WR, High KP, Houghton P, Jacobson N, Kirsner RS, Kovacs EJ, Margolis D, McFarland Horne F, Reed MJ, Sullivan DH, Thom S, Tomic-Canic M, Walston J, Whitney JA, Williams J, Zieman S, Schmader K. Chronic wound repair and healing in older adults: current status and future research. *J Am Geriatr Soc*. 2015 Mar;63(3):427-38. ([Link](#))

PRT Members requested staff respond to several questions (numbered below) related to PT/OT billing for application of skin substitutes, scope of practice, and debridement. Staff circulated the responses to PRT members via email on March 23, 2018.

1. The most important thing we need to clarify about reimbursement for wound care products is whether PT/OTs can currently bill and be paid for the skin substitute products under Medicare FFS and if not, why not (i.e., is there a coverage document somewhere that describes who can and can't bill and that explains why PTs/OTs can't bill for products that others can). Then we also want to confirm that all of these products are paid based on invoice cost for those who can bill for them.

The skin substitute products are only billed in conjunction with codes for application of a skin graft—codes 15271-8 and C5271-8. Reimbursement for skin substitutes is packaged with the application procedure. CMS classifies skin substitutes as high cost and low cost based on ASP. The [2018 update to OPBS](#) has a table with high/low cost products, updated annually—providers bill 1527X if they use a high-cost product or C527X for a low-cost product. In 2018, none of the substitutes qualifies for pass-through status (Puraply's pass-through status (Q4172) expired 12/31/17).

The submitter requested the ability to bill for C527X (low cost) codes. CMS confirmed that these are OPBS codes and must be billed in a hospital (or an ASC). CMS stated that PTs/OTs may be able to bill these codes in a hospital setting and/or under the guidance of physicians.

We did find some coverage documents that provide explanations for policies re billing for skin substitutes. I took away two main arguments from the MACs for restricting billing. The MAC viewed these codes as surgery that should be performed by physicians or other qualified health professionals (NPs, clinical nurse specialists, and PAs—no mention of PT/OTs). Medicare classifies these codes (TOS) as [Type 2, Surgery](#). The MAC also stated the survivability of the skin substitute was jeopardized by inadequate handling. See [United Healthcare](#), [Novitas](#) for examples.

2. The scope of practice issue relates specifically to “sharp debridement,” not non-invasive debridement, and there is also a distinction within sharp debridement between “surgical debridement” vs. “conservative sharp debridement” and we need to understand whether scope of practice permits the latter. I doubt that surgical debridement is within scope for PTs/OTs anywhere, but conservative sharp debridement may be.

Below is a summary of different codes referenced in application of skin substitutes and wound care:
[15002-15005:](#)

Description: Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; first 100 sq cm or 1% of body area of infants and children

No indication that PTs/OTs can bill for these codes; submitter didn't ask to bill for them.

From [AAPC commentary](#): “Codes 15002-15005 apply specifically to describe the work of “preparing a clean and viable wound surface for placement of an autograft, flap, skin substitute graft or for negative pressure wound therapy,” according to CPT® guidelines. Surgical prep codes would not be reported for removal of nonviable tissue or debris in a chronic wound when it is left to heal by

secondary intention. When a wound requires serial debridement, report active wound management (97597-97598) or debridement (11042-11047). If a wound requires negative pressure wound therapy, 15002-15005 are applicable in addition to 97605-97606.”

97597/97598 (active wound management)

Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less
PTs/OTs can bill for this, subject to state scope of practice and LCDs; see [CGS LCD on outpatient therapy](#)
Some background: stemming from [an OIG report](#) that found overuse and poor coding of codes 11040 and 11041 (debridement, skin—partial and full thickness), CMS deleted these codes in 2011 and directed all clinicians to use 97597/98 instead. If PTs/OTs bill them, they need to use the G-modifier and the codes are subject to the therapy cap; billing by other providers is not subject to therapy caps.

97602 (non-selective debridement):

Description: Removal of devitalized tissue from wound(s), non-selective debridement, without anesthesia (eg, wet-to-moist dressings, enzymatic, abrasion, larval therapy), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session
PTs/OTs can bill for this, subject to state scope of practice (also referenced in CGS LCD)

11042-11047 (subcutaneous/excisional debridement)

Description: Debridement, subcutaneous tissue (includes epidermis and dermis, if performed); first 20 sq cm or less

Notes: (For debridement of skin [ie, epidermis and/or dermis only], see 97597, 97598)

<http://www.hcpro.com/HIM-283163-8160/Differentiate-between-types-of-wound-debridement.html>

Several coverage documents indicate that PTs/OTs cannot bill for these 1104X codes

[Noridian](#) LC article on coverage for debridement restricts 11000 series to physicians, NPPS, and clinical nurse specialists (subject to scope of practice)

The [CGS LCD on debridement](#) (L34032) specifically excludes PT/OTs.