GraftJacket® and Outpatient Wound Center Reimbursement

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Objectives

1. Understand the basics of wound center ***facility*** and ***physician*** reimbursement
2. Understand Graftjacket reimbursement for both the physician and facility (and compare it to another bioengineered skin)
3. Understand how changes to Medicare might affect the use of Graftjacket (e.g. RAC audits and the implementation of Obamacare)

Wound Center Billing is COMPLEX

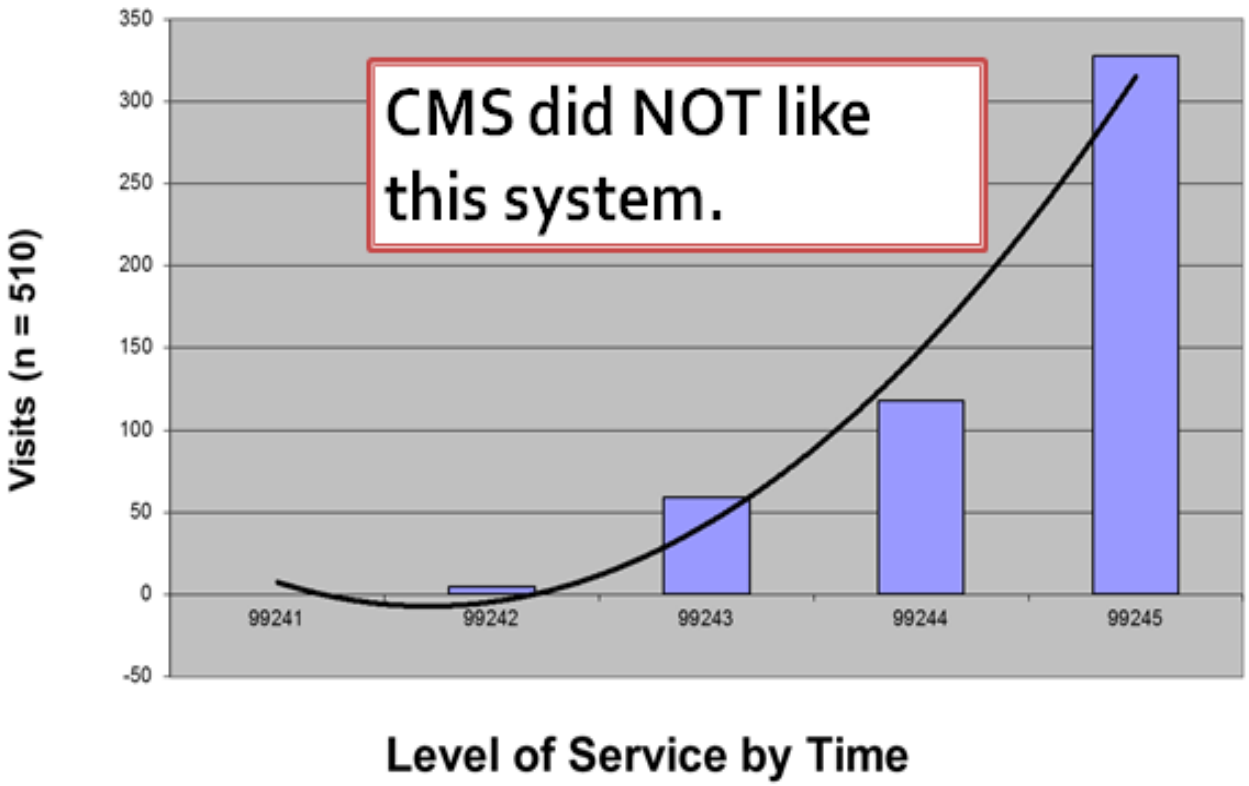
- Physicians are still mostly independent practitioners but there is a movement to employ wound center doctors (by hospitals and management companies)
- Hospitals do a terrible job of billing outpatient care because they don't understand it is different than in-patient care.
  - Many busy wound centers losing money when they shouldn't due to poor billing practices (they don't understand their own billing!)
- The "drivers" for product use on both the clinician and facility sides will surprise you and they are about to change.

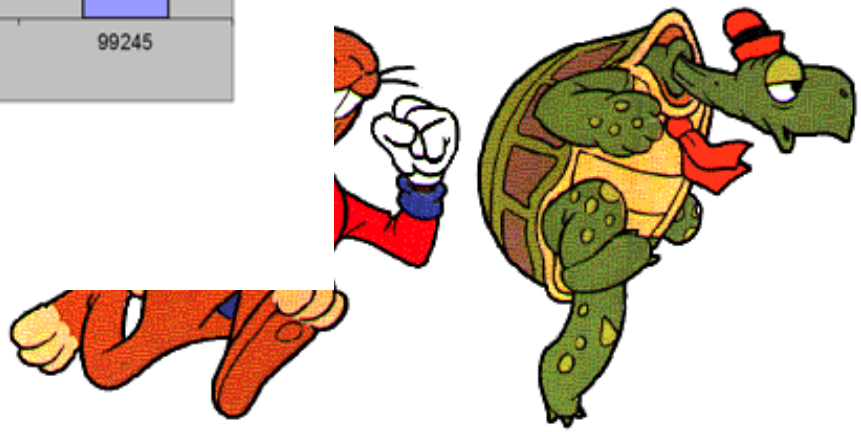
Facility reimbursement in Hospital Based Wound Centers

- In 1999 CMS Created the Hospital Outpatient Prospective Payment System (HOPPS) but had no way to quantify the services rendered
  - CMS repurposed the *physician* Evaluation and Management (E/M) Codes for the hospital resources used in support of the physicians
  - Per the Federal Register, each facilit
    a system for mapping the provided
- Physicians provide patient care, but hospitals employ staff and contribute resources to support the services provided by the physician.

Facility billing

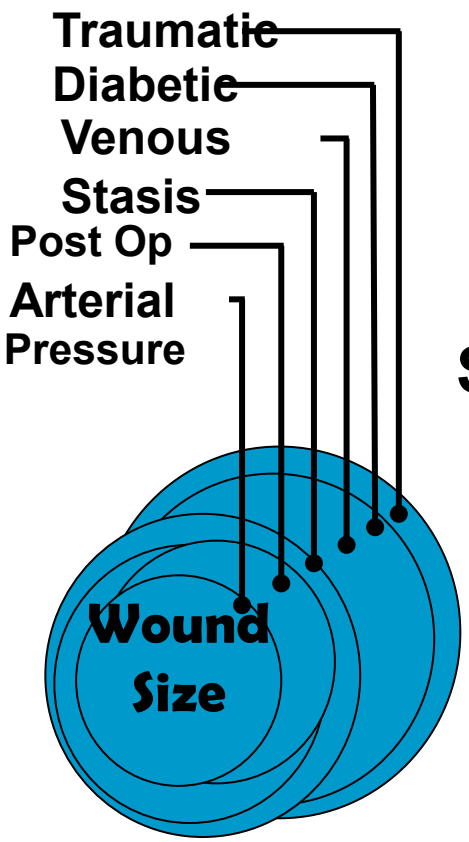
Facility Billing by Time



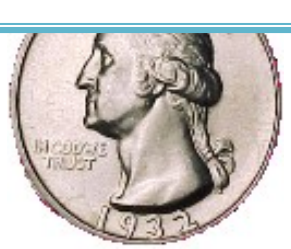


- Rewarded inefficiency.

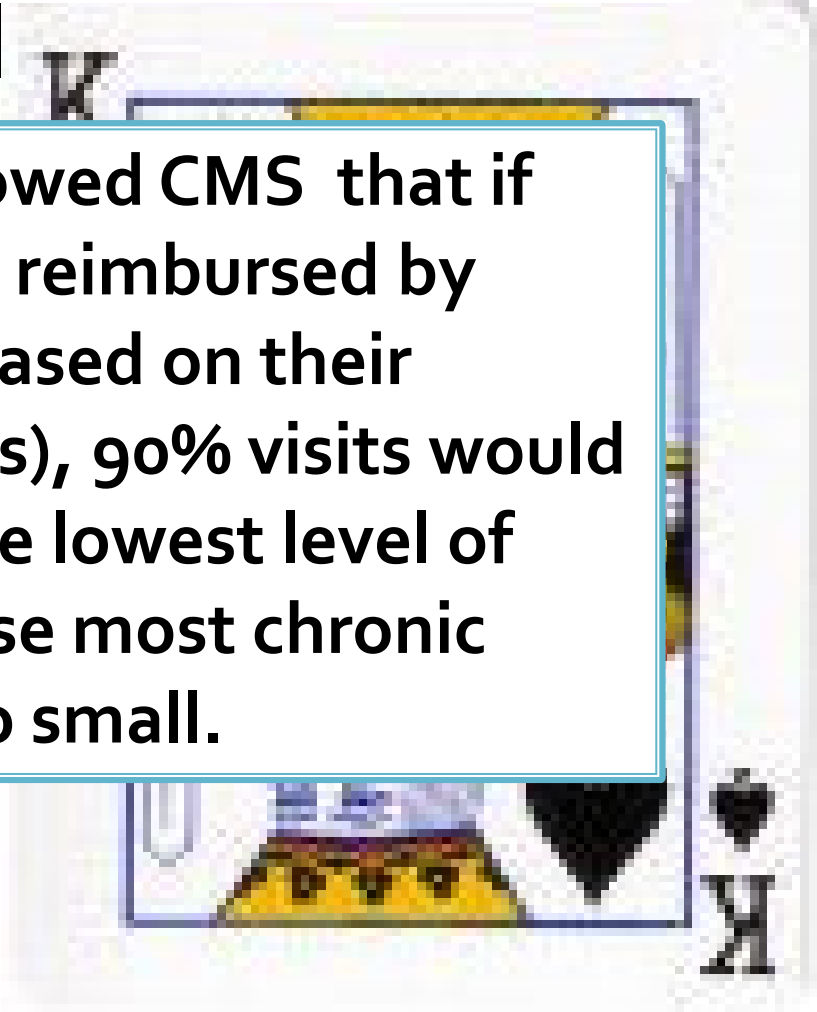
In 2005, CMS proposed facility reimbursement by WOUND SIZE



Intellicure showed CMS that if facilities were reimbursed by wound size (based on their proposed sizes), 90% visits would be billed at the lowest level of service because most chronic wounds are so small.



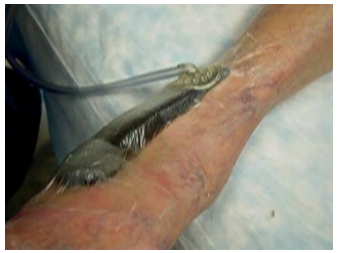
Quarter, 4.44 cm²
Approximately Level 1

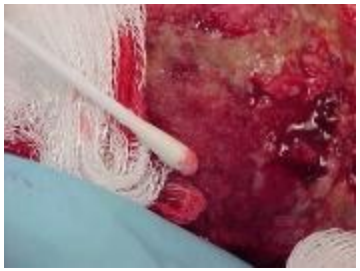


Playing Card, 56.45 cm²
Approx. Level 3 (>50.1 cm²)

2005: Intellicure Developed Acuity Scoring for Facility Reimbursement

- Evaluated all possible services rendered in the wound care setting which did not have separate billing code.
- Attached numeric value to each of those activities
- Defined a score (0-200) that "tracks" to a level of service

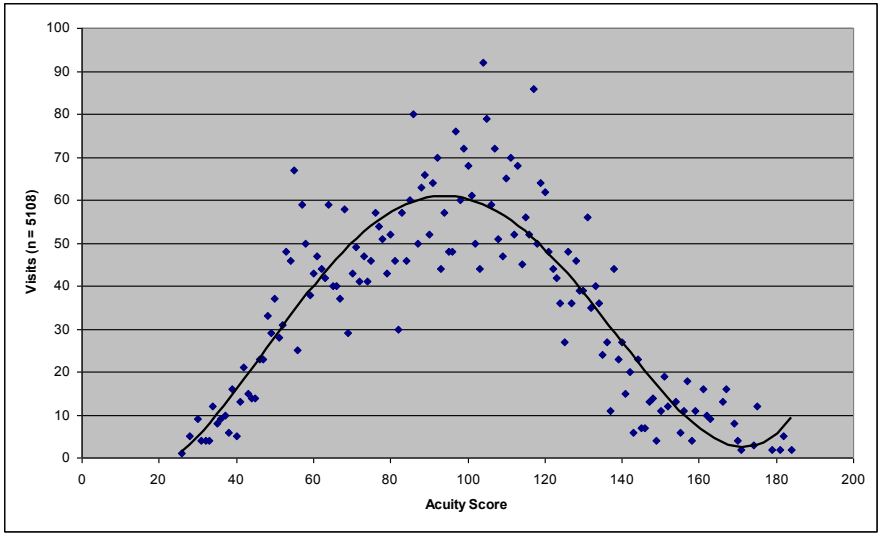




Intellicure Acuity Scoring as billing method Accepted by CMS

- Method of Arrival (ambulatory/stretcher)
- Additional Resource Utilization (isolation, translator)
- Patient Assessment (history, general physical exam, risk, etc)
- Patient Process (coordination of care, education)
- Problem Focused Activities
  - Wound Care (measuring, dressing application)
  - Edema Management
  - Ostomy
- Other Focused Interventions
  - Diabetes Management
  - Nutrition
- General Procedures (injections, cast removal)
- Testing (hand held Doppler, culture, blood draw)
- Departure Instructions
- Departure Disposition (to home, to ER, etc)

Intellicure validated Acuity Scoring for Facility Billing (n=4,589)

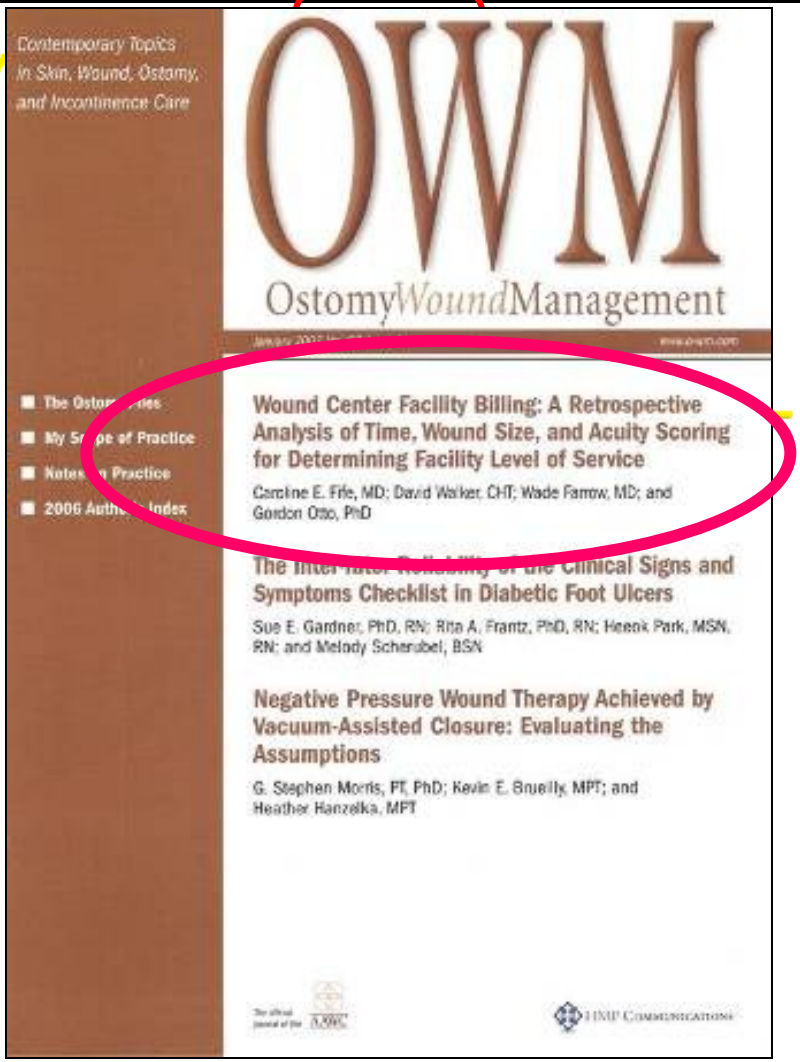


Mean: 95.6

Standard Deviation: 30.0

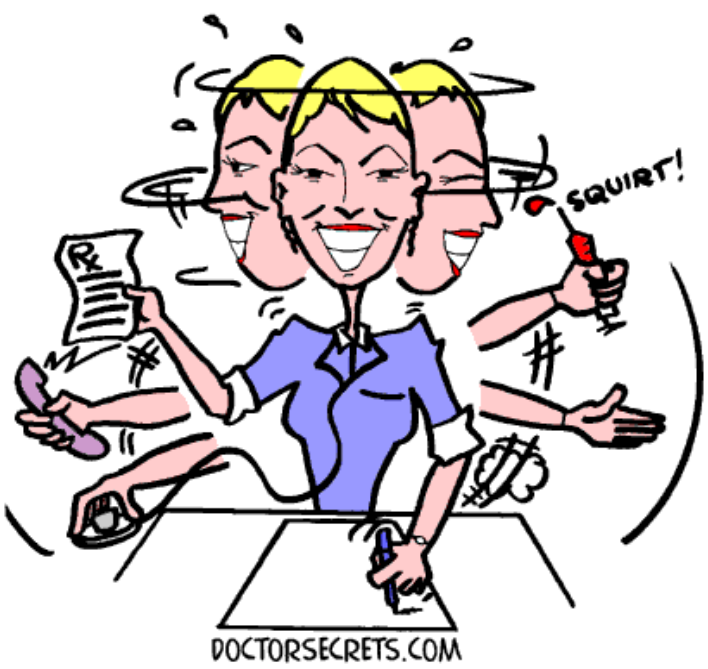
Correlation Coeff.: 0.881

The majority of wound centers have used acuity scoring for non procedure billing since 2005



PHYSICIAN Billing of E/M Services

1. The patient's history (3 components)
   - History of Present Illness (HPI)
   - Past Medical, Family, and Social History (PMH, FH, SH)
   - Review of Systems (ROS)
2. The physical examination
3. The physician's medical decisio making



Each Key Component contains four levels of difficulty.

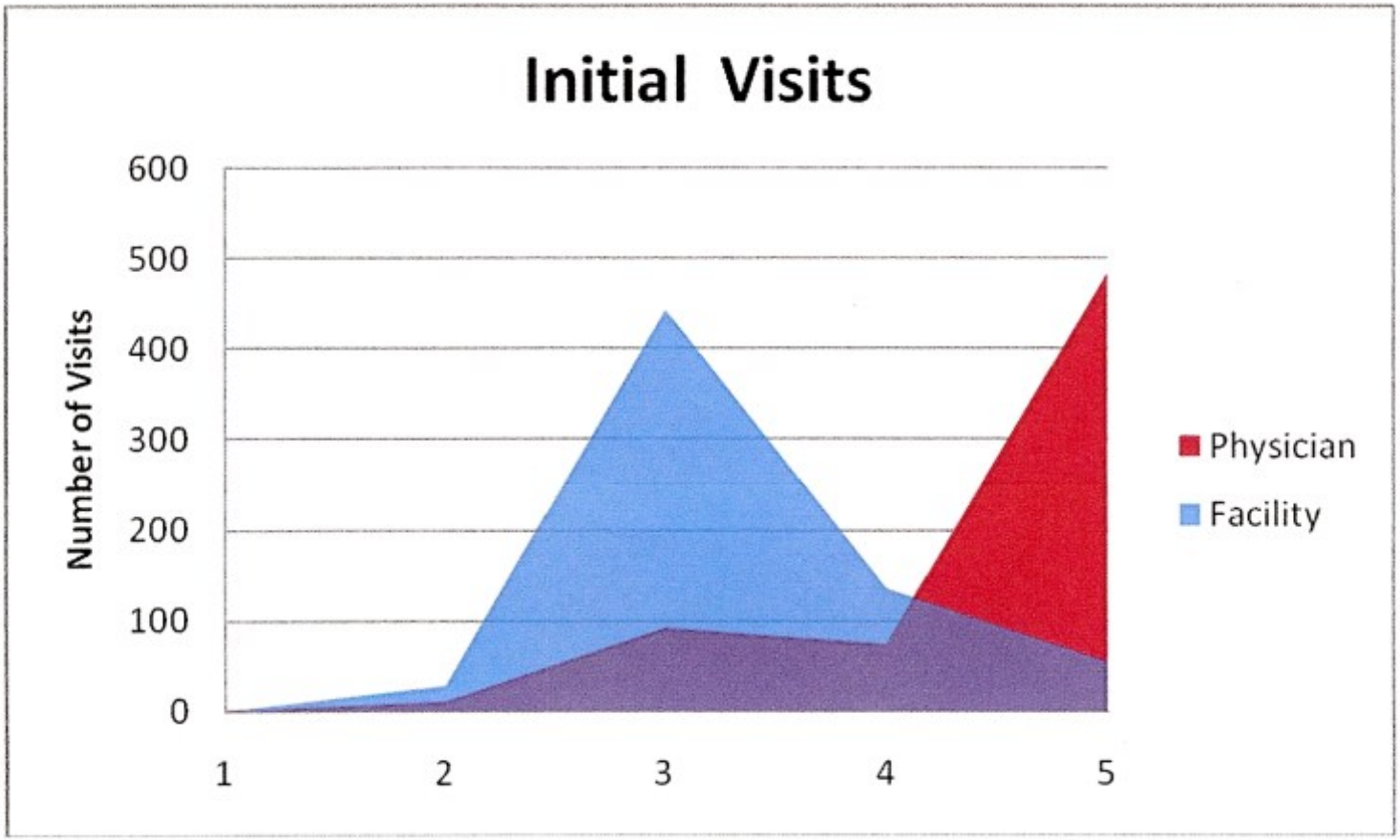
Physician Billing of E/M Services: It's Complicated

- The 1997 Documentation book requires 53 pages to explain this system
- The American College of Physicians noted that before an Internist using the 1997 Guidelines could decide on an E/M service code, 42 choices would have to be considered.
- Thus, there are 6,144 possible combinations representing the number of ways an office visit for a new patient can evolve and be classified*

1997 Documentation Guidelines for Evaluation and Management Services

(*May, 25, 2000 "Statement to the Health Task Force Committee on the Budget, United States House of Representatives, Medicare Regulatory Burden Imposed on Physicians," http://www.acponline.org/hpp/hbstmt.htm).

Wound Center Physicians and Facility Use the Same CODES but don't bill the same Services



Physician levels of service do not follow normal distribution and are skewed toward higher levels of service for the initial

Big Cuts are Coming to E[illegible] Services

GOVERNME

27% M[illegible] Congre[illegible]

A showdo[illegible] effect Jan.

By DAVID [illegible]

PRINT | E-M[illegible]

Washingt[illegible] was defus[illegible] only mai[illegible] again to a[illegible]

The Ho[illegible] extension[illegible] physician[illegible] provide t[illegible] longer-te[illegible] March 1.

Medicare CY 2011 Payments for Visit Services
Current vs. Proposed New Policy

CPT Code		Doctor		Hospital		nt
						cent
992[illegible]						%
992[illegible]						%
992[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	%
99204	$158.33	$126.39	$128.48	$31.94	$96.54	75%
99205	$197.06	$162.41	$168.92	$34.65	$134.27	80%
99211	$19.71	$9.17	$52.36	$10.54	$41.82	80%
99212	$41.45	$25.14	$75.13	$16.31	$58.82	78%
99213	$68.97	$49.27	$75.13	$19.70	$55.43	74%
99214	$102.27	$75.77	$99.71	$26.50	$73.21	73%

More on what this means in a minute

75% of Physician and Facility Revenue is Derived from PROCEDURES

Clinic	Global Revenue E/M ($)	Global Revenue Procedure ($)	Total Global Revenue ($)	Revenue Related to Procedures (%)
Texa				
New				
Sou Car				
TOT				

Revenue from PROCEDURES represents 74% of the total for both the physician and the facility, and this is where Graftjacket comes in

How do clinicians get paid for procedures?

Physician Procedural Revenue

- The Resource-Based Relative Value Scale (RBRVS) method is predicated on a "Total RVU" system.
  - Includes the Physician Work RVU, the Practice Expense RVU and a Malpractice Expense RVU.
- Total RVU is adjusted by locality according to the Geographic Practice Cost Index (GPCI), before being multiplied by the current Conversion Factor (CF) to calculate the reimbursement for a service.

Procedural Revenue Determined By RVUs

Medicare Physician Allowable	HCPCS Code	SHORT DESCRIPTION	PROC STAT	PCTC	WORK RVU	TRANSITIONED NON-FAC PE RVU	FULLY IMPLEMENTED NON-FAC PE RVU	TRANSITIONED FACILITY PE RVU	FULLY IMPLEMENTED FACILITY PE RVU	MP RVU
$ 24.89	99201	Office/outpatient visit new	A	0	0.48	0.73	0.74	0.24	0.25	0.04
$ 47.24	99202	Office/outpatient visit new	A	0	0.93	1.13	1.17	0.44	0.45	0.07
$ 72.06	99203	Office/outpatient visit new	A	0	1.42	1.53	1.58	0.64	0.66	0.14
$ 122.26	99204	Office/outpatient visit new	A	0	2.43	2.06	2.13	1.07	1.12	0.23
$ 156.93	99205	Office/outpatient visit new	A	0	3.17	2.42	2.47	1.34	1.39	0.27
$ 8.89	99211	Office/outpatient visit est	A	0	0.18	0.39	0.38	0.08	0.08	0.01
$ 24.27	99212	Office/outpatient visit est	A	0	0.48	0.73	0.74	0.22	0.22	0.04
$ 47.98	99213	Office/outpatient visit est	A	0	0.97	1.03	1.07	0.42	0.44	0.07
$ 73.68	99214	Office/outpatient visit est	A	0	1.5	1.46	1.5	0.64	0.66	0.1
$ 103.61	99215	Office/outpatient visit est	A	0	2.11	1.86	1.91	0.9	0.94	0.14

Procedural Revenue Determined By RVUs

	HCPCS Code	SHORT DESCRIPTION	PROC STAT	PCTC	WORK RVU	TRANSITIONED NON-FAC PE RVU	FULLY IMPLEMENTED NON-FAC PE RVU	TRANSITIONED FACILITY PE RVU	FULLY IMPLEMENTED FACILITY PE RVU	MP RVU
56.89	11042	Deb subq tissue 20 sq cm/<	A	0	1.01	2.04	2.31	0.61	0.69	0.13
150.86	11043	Deb musc/fascia 20 sq cm/<	A	0	2.7	3.65	3.65	1.5	1.5	0.45
225.5	11044	Deb bone 20 sq cm/<	A	0	4.1	4.59	4.59	2.13	2.13	0.72
25.64	11045	Deb subq tissue add-on	A	0	0.5	0.59	0.59	0.18	0.18	0.11
52.74	11046	Deb musc/fascia add-on	A	0	1.03	0.9	0.9	0.41	0.41	0.18
93.33	11047	Deb bone add-on	A	0	1.8	1.43	1.43	0.74	0.74	0.33
$ 23.08	97597									
$ 10.86	97598									

	HCPCS Code	SHORT DESCRIPTION	PROC STAT	PCTC	WORK RVU	TRANSITIONED NON-FAC PE RVU	FULLY IMPLEMENTED NON-FAC PE RVU	TRANSITIONED FACILITY PE RVU	FULLY IMPLEMENTED FACILITY PE RVU	MP RVU
115.06	99183	Hyperbaric oxygen therapy	A	0	2.34	.75	3.86	0.91	0.94	0.26

Procedural Revenue Determined By RVUs

The work component of BSS is more than a subQ debridement, more than a new patient evaluation, and slightly less than HBOT.

$ 16.68	15272	Skin sub graft t/a/l add-on	A	0	0.33	0.43	0.43	0.14	0.14	0.04
$ 199.22	15273	Skin sub grft t/arm/lg child	A	0	3.5	4.59	4.59	2.03	2.03	0.62
$ 42.40	15274	Skn sub grft t/a/l child add	A	0	0.8	1.15	1.15	0.4	0.4	0.1
$ 97.21	15275	Skin sub graft face/nk/hf/g	A	0	1.83	2.41	2.41	0.85	0.85	0.31
$ 23.95	15276	Skin sub graft f/n/hf/g addl	A	0	0.5	0.43	0.43	0.17	0.17	0.06
$ 207.03	15277	Skn sub grft f/n/hf/g child	A	0	4	4.17	4.17	1.76	1.76	0.59
$ 52.52	15278	Skn sub grft f/n/hf/g ch add	A	0	1	1.28	1.28	0.48	0.48	0.13

Physician Reimbursement for Application

- When using code 15273=
  - $199.22 in Harris County (varies slightly by region)
- This is determined by the RVU
- Will be the same for all bioengineered skin products!

Facilities get an "Application fee" as well, based on RVUs

CPT	Description	SI	APC	Relative Weight	Payment Rate
15271	Skin sub graft trnk/arm/leg	T	0134	3.5264	$251.48
15272	Skin sub graft t/a/l add-on	T	0133	1.2024	$85.75
15273	Skin sub grft t/arm/lg child	T	0135	5.5162	$393.38
15274	Skn sub grft t/a/l child add	T	0134	3.5264	$251.48
15275	Skin sub graft face/nk/hf/g	T	0134	3.5264	$251.48
15276	Skin sub graft f/n/hf/g addl	T	0133	1.2024	$85.75
15277	Skn sub grft f/n/hf/g child	T	0135	5.5162	$393.38
15278	Skn sub grft f/n/hf/g ch add	T	0134	3.5264	$251.48

Graftjacket is $393.38
per application, but it is the same
for all bioengineered skin products

What We Have Learned So Far

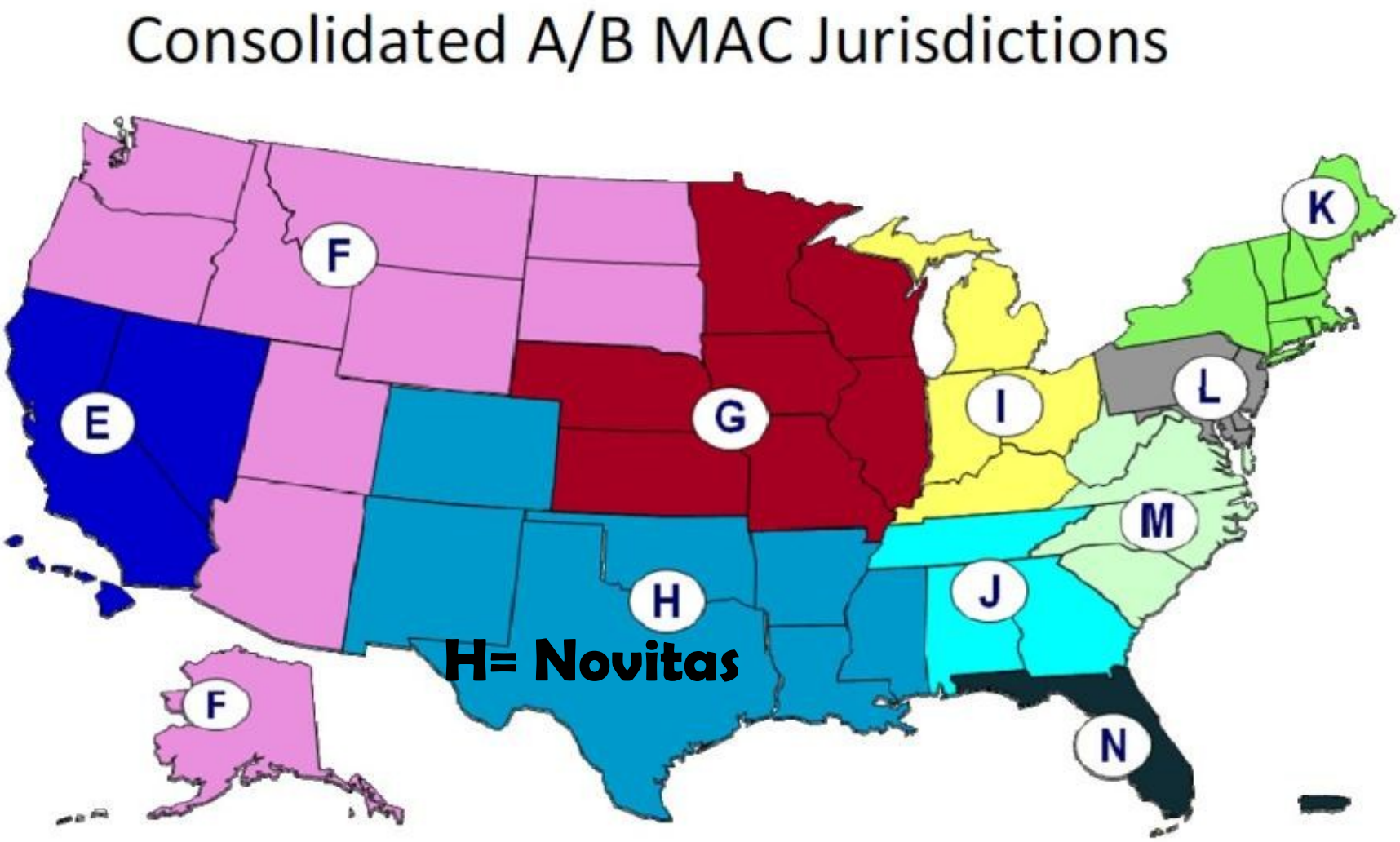
- Revenue for both the hospital (facility) and the physician at the moment is still VOLUME based.
- ~75% of the revenue for both is based on Procedures (like Graftjacket).
  - The more Graftjacket applications, the better, from that perspective.
- For the physician and the facility, reimbursement for Graftjacket ***application*** (per procedure) is the same for all bioengineered tissues.

How Does a Clinician Get to Use Graftjacket (or NOT)?

- CMS creates a coverage policy (usually after FDA clearance/approval)
- Medicare Administrative Carriers (MACs) are the Fiscal Intermediaries (FIs) that implement the CMS coverage policy
  - Create the fine print that determine the specifics of documentation and coding necessary for payment
  - Often results in regional differences in coverage for a product

Let's look at an LCD and see what it means for Graftjacket

10 Medicare Fiscal Intermediaries



Novitas "LCD" for Bioengineered Skin Substitutes

NOVITAS SOLUTIONS

INNOVATION IN ACTION
A CMS CONTRACTOR • ISO 9001-2008 CERTIFIED

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LCD L32622 - Bioengineered Skin Substitutes

Print

Contractor Information

Contractor Name:	Contractor Number(s):	Contractor Type:
Novitas Solutions, Inc.	04911, 07101, 07102, 07201, 07202, 07301, 07302, 04111, 04112, 04211, 04212, 04311, 04312, 04411, 04412	MAC Part A & B

Go to Top

LCD Information

Document Information

LCD ID Number	**Primary Geographic Jurisdiction**
L32622	Arkansas, Louisiana, Mississippi, Colorado, Texas, Oklahoma, New Mexico
LCD Title	**Oversight Region**
Bioengineered Skin Substitutes	Central Office
Contractor's Determination Number	**Original Determination Effective Date**
L32622	For services performed on or after 08/13/2012
AMA CPT/ADA CDT Copyright Statement	**Original Determination Ending Date**

https://www.novitas-solutions.com/policy/jh/l32622-r4.html

GraftJacket® Indications & Limitations per Novitas LCD

- ***GraftJacket® (Q4107) Indications:***
  Full-thickness diabetic foot ulcers
- ***GraftJacket®* (Q4107) Limitations:**
  Medicare payment for *GraftJacket®* is limited to 1 application per ulcer.

Apligraf® Indications & Limitations per Novitas LCD

- ***Apligraf® (Q4101) Indications:***
  - Neuropathic diabetic foot ulcer
  - Venous stasis ulcer.
- ***Apligraf® (Q4101) Limitations:***
  - 5 applications per ulcer

Dermagraft® Indications & Limitations per Novitas LCD

- ***Dermagraft®* (Q4106) Indications:** Treatment of full-thickness diabetic foot ulcers.
- ***Dermagraft® (Q4106) Limitations:***
  - "Studies have documented that, for Q4106, survival of the dermal substitute decreases significantly when the 24 steps noted in the FDA labeling are not followed, therefore ***the 24 steps must be followed and documented***."
  - 8 applications per ulcer.

Coverage Policies for Graftjacket are Different in other MACs

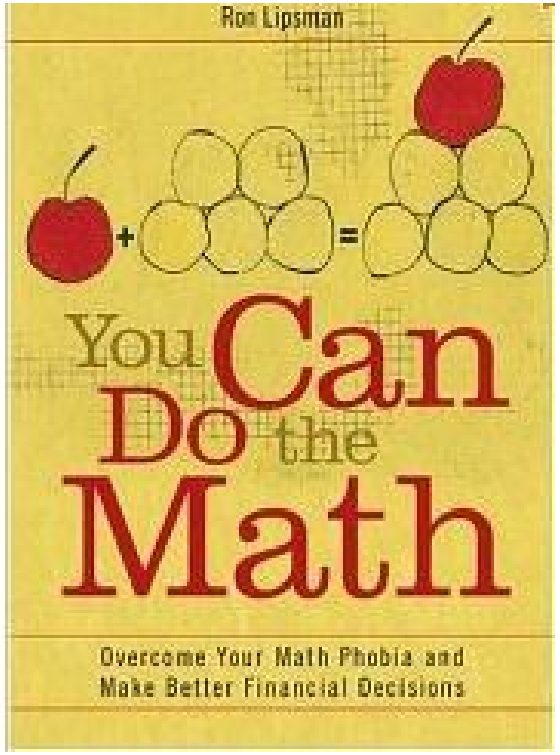
A single application of Acellular Dermal Tissue Matrix for any particular ulcer is usually all that is required to achieve wound healing in those wounds that are likely to be helped by this therapy. Treatment with GRAFTJACKET® Regenerative Tissue Matrix-Ulcer Repair is usually expected to last no more than twelve (12) weeks and to involve a maximum of two applications for any ulcer that initially qualifies for treatment.

WPS covers 2 applications of Graftjacket per wound

http://www.apligraf.com/professional/pdf/Wisconsin_Physician_Services.pdf

Potential *Physician* Revenue for Bioengineered Skin *Per Patient*

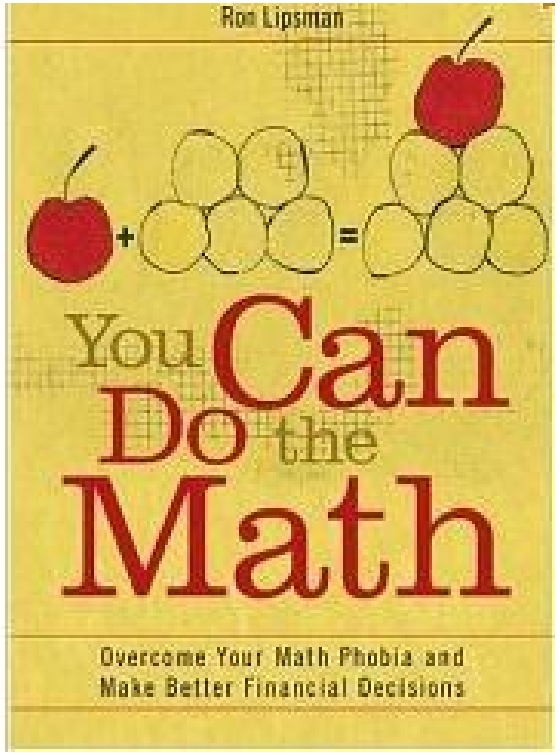
- 8 Dermagrafts = $1,593.76
- 5 Apligrafts = $ 996.10
- 1 Graftjacket = $ 199.22



There is some fine print in the LCD that matters. Subsequent applications are not covered if the wound does not improve from the first one.

Potential *Facility* Revenue for Bioengineered Skin *Per Patient*

- 8 Dermagrafts = $3,147.04
- 5 Apligrafts = $ 5,966.90
- 1 Graftjacket = $ 393.38



Thus, on a per patient basis, Graftjacket is at a disadvantage compared to the other options in terms of its ability to produce revenue.

Now for the Part You Really Might Not Want to Know

What Even Most Clinics Don't Know About Facility Revenue for Bioengineered Skin

- In 2011, Up a Creek Wound Center's hospital pharmacy
- This is not an unusual example! This happens a lot. I have not explained the complex billing mechanism or the wastage fee.
- being entered by ***either*** pharmacy or the
- when the product was placed on a patie
  - Medicare requires the product to be reporte
    claim as the application or no payment for either the application or the product is made.

Graftjacket List Price vs. 2013 Reimbursement

- CMS reimbursement for Graftjacket
  = $99.17 per cm^2
- GJ44 4x4cm List Price (16 cm^2): $1721
  - Loss of $134.00
- GJ48 4x8cm List Price (32 cm^2): $3441
  - Loss of $268.00

The Truth About Graftjacket Pricing

- You need to offer an 8% discount on product for the clinic to break even on the product cost.

Product	List Price	20% discount	Medicare Reimbursement per sq cm	sq cm	Anticipated Reimbursement per sheet	Difference between list price and reimbursement	Difference between 20% discount price and reimbursement	Breakeven discount
Graftjacket 4X4 cm	$ 1,721	$ 1,376.80	$99.17	16	$1586.72	$ (134)	$ 209.92	8%
Graftjacket 4X8 cm	$ 3,441	$ 2,752.80	$99.17	32	$3173.44	$ (268)	$420.64	8%

The LCD Fine Print: Huge $$ At Risk

The provisions (products and procedures) of this L
wound preparation and material application to chr
porcine dermal xenografts. Additionally, the provis
tissue reconstruction and/or replacement (e.g.tenc

**The following general indications and limitati
physician services related to skin substitute a**

Indications - all covered bioengineered skin s

- Provided in accordance with the material's Food an
- Applied to partial- or full-thickness wounds (see inc
  exposed bone or sinus tracts.
- Applied to wounds that have demonstrated a failed
  chronic wounds. For initial applications of skin subs
  size or depth or for which there has less than 30%
  - Elimination of underlying cellulitis, osteomyeli
  - Elimination of edema.
  - Appropriate debridement of necrotic tissue.
  - Appropriate non-weight bearing and/or other
  - Provision of appropriate wound environment t

- Provided in association with patient care (including
  wound management (including appropriate physici
- Applied to wounds reasonably expected to heal in t
  substitute/replacement and not applied to wounds
- Applied to wounds that are clean and free of infecti
- Applied to wounds of reasonable size given the clin
  wounds (smaller than 1.0 cm2 or 1cm in smallest c
  but otherwise healable. Use on small wounds that l
- Only applied to wounds with adequate circulation/o
  acceptable peripheral pulses and/or Doppler toe sig

Novitas "LCD" for Bioengineered Skin Substitutes requires documentation that:

- The wound has failed no fewer than 4 weeks of conservative wound-care . . . defined as an ulcer that has increased in size or depth or for which there has been less than 30% closure from baseline.
- Conservative measures include:
  - Elimination of underlying cellulitis, osteomyelitis, infection
  - Elimination of edema.
  - Appropriate debridement of necrotic tissue.
  - Appropriate non-weight bearing and/or other means for off-loading pressure.
  - Provision of appropriate wound environment to promote healing.

Novitas "LCD" for Bioengineered Skin Substitutes requires documentation that:

- BSS is applied to wounds **reasonably expected to heal**
- Applied to wounds that are clean and free of infection.
- Applied to wounds of reasonable size
  - Not to wounds smaller than 1.0 cm^2 unless the medical record clearly demonstrates the wound to be refractory to conservative treatment
- Only applied to wounds with adequate circulation/oxygenation as evidenced by physical examination (presence of acceptable peripheral pulses and/or Doppler toe signals and/or Ankle-Brachial Index (ABI) of no less than 0.65).

Novitas "LCD" for Bioengineered Skin Substitutes

- **ALL covered bioengineered skin substitutes must be:**
  "Provided in accordance with the material's Food and Drug Administration- (FDA) approved package label."

This exact verbiage has to be in the procedure note or the clinic/MD is at risk of repayment on post-payment review.

Novitas "LCD" for Bioengineered Skin Substitutes Specifies:

- "Applied to partial- or full-thickness wounds (see individual product information for labeled indications) **not** involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tracts."

Scaffolds, antibiotics and wound pressure show promise in treating diabetic foot sores, **Endocrine Today**, January 2006

So, this type of use will not be covered per the Novitas LCD

ADDRESSOGRAPH

PROCEDURE NOTES

Procedure Date: 12/27/2012

Procedure: GraftJacket Application; trunk, arms, legs, and ankles

In total, there are ~20 specific points of documentation that are required (some specifying what is NOT present like infection) and some specifying what IS present like adequate perfusion. True for all BSS (Graftjacket, Apligraf, Dermagraft, Oasis, etc.). If these are not in the note, the clinician and clinic are at risk of repayment under audit.

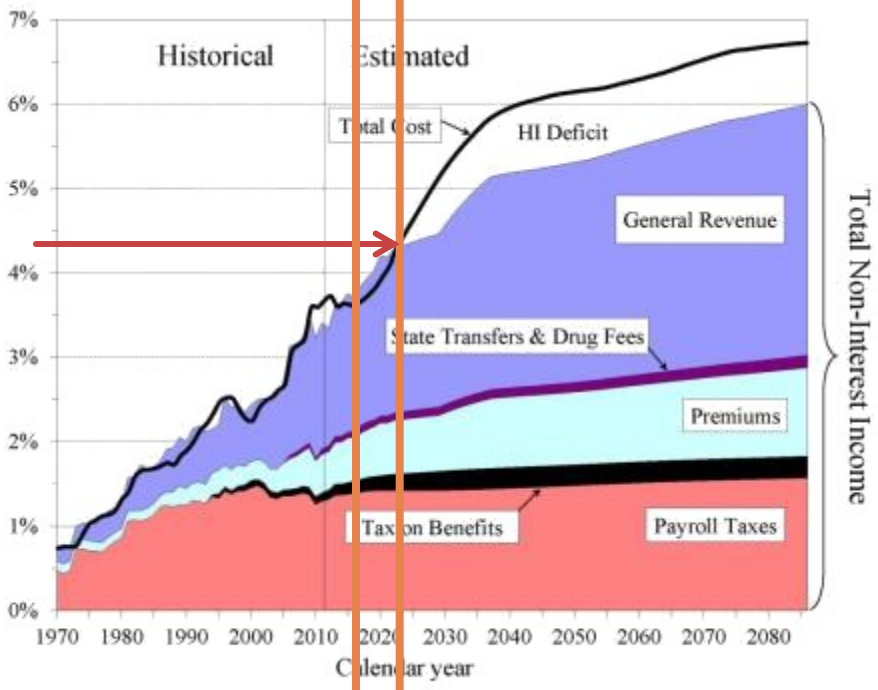
Dx 1. 707.12 Ulcer of calf

Signature: _____

Test Doctor, MD

Impending Medicare Bankruptcy

- Medicare will go bankrupt in either 2024 or 2016, depending on how you calculate the effect of Obamacare which will hasten its demise (2012 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds).
- "Improper payments" are a significant contributor to this problem.
  - >30% of Medicare payments are "improper"



Medicare Cost and Non-Interest Income by Source as a Percentage of GDP

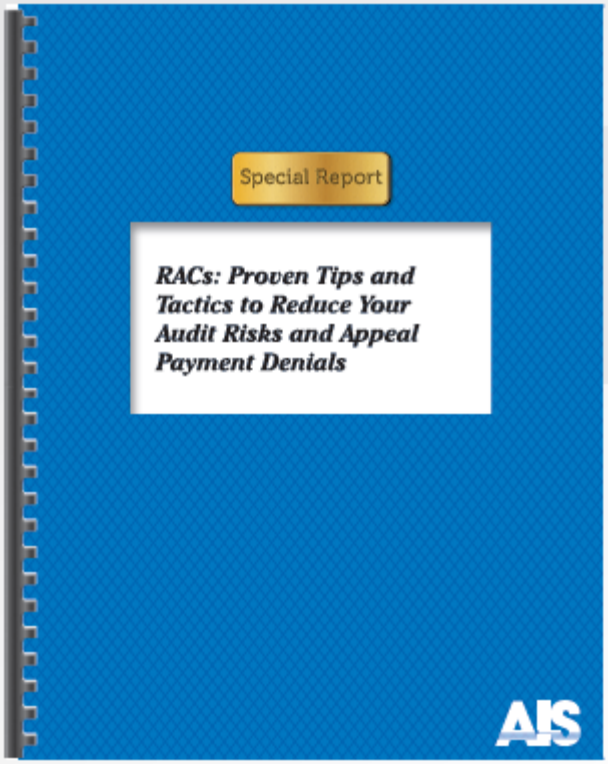
Recoupment Programs are all that is keeping Medicare Afloat

- RAC: Recovery Audit Contractors
- Mission: reduce Medicare improper payments (over or underpayments)
- Work on commission
  - Receive 9% - 12.5% of everything they *collect*
  - Can go back as far as 36 months
- From March 2005-March 2008, the RACs corrected more than $1.03 billion in Medicare improper payments.

The original "rack" auditor (which might have been easier)

Wound Care is Among the "High Risk" and Target Areas for RAC Audits

From The AIS Bookshelf:
High-Risk and Target Areas



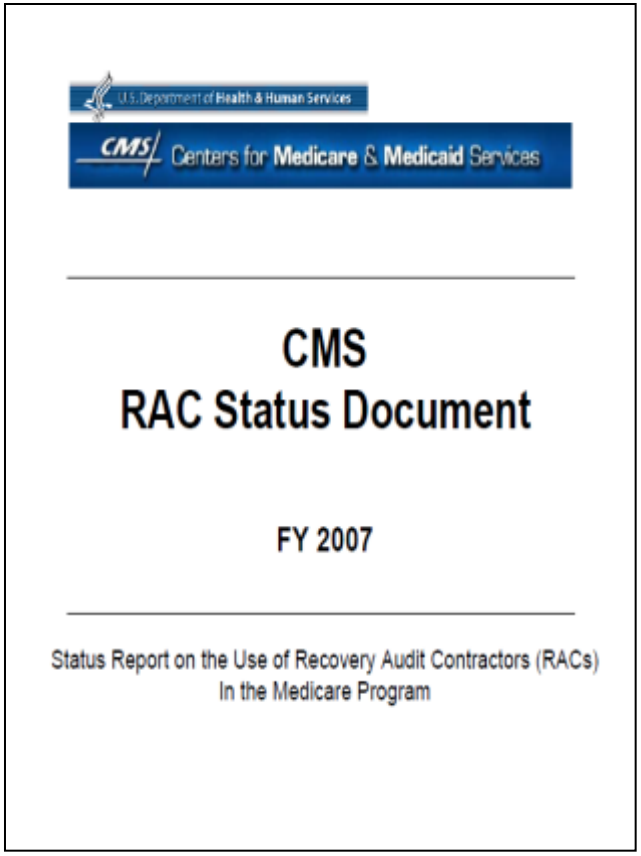
This PDF includes a 34-page chapter on the *"High-Risk and Target Areas"* from the AIS report ***RACs: Proven Tips and Tactics to Reduce Your Audit Risks and Appeal Payment Denials.***

For more information and to order the entire 80-page report, click here.

http://aishealth.com/sites/all/files/comp_brac.pdf

RAC Auditors Hit Excisional Debridement

- "Corrective Actions" (per report)
  - Hospitals can be more careful when submitting claims for excisional debridement
  - Medicare claims processing contractors can remind hospitals about the importance of following the coding clinic guidelines when submitting claims for excisional debridement.


U.S. Department of Health & Human Services

CMS Centers for Medicare & Medicaid Services

CMS
RAC Status Document

FY 2007

Status Report on the Use of Recovery Audit Contractors (RACs)
In the Medicare Program

http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program/downloads/2007RACStatusDocument.pd

RAC Overpayment Collections for Debridement 2007 (Inpatient)

Table 2-6
Top Services with RAC-Initiated Overpayment Collections (NET OF APPEALS) – FY 2007

Type of Provider	Description of Item or Service	Amount Collected Less Cases Overturned on Appeal	Claims Found in Error Less Cases Overturned on Appeal	Location of Problem
Inpatient Hospital	Excisional Debridement	$ 30.5 m $ 3.2 m $ 2.5 m		
	IRF services following joint replacement surgery	$ 20.8 m	1,833	CA
	Heart Failure and Shock	$ 7.8 m $ 2.0 m $ 9.5 m	835 306 2190	NY CA FL
	Surgical Procedures in Wrong Setting	$17.1 m	1,610	NY
	Respiratory System Diagnoses with Ventilator Support	$ 9.5 m $ 4.1 m $ 1.7 m	577 266 123	NY CA FL
	Extensive OR procedures Unrelated to Principal Diagnosis	$ 3.9 m $ 3.1 m $ 1.5 m	299 264 123	NY CA FL

$Total 37.5 Million

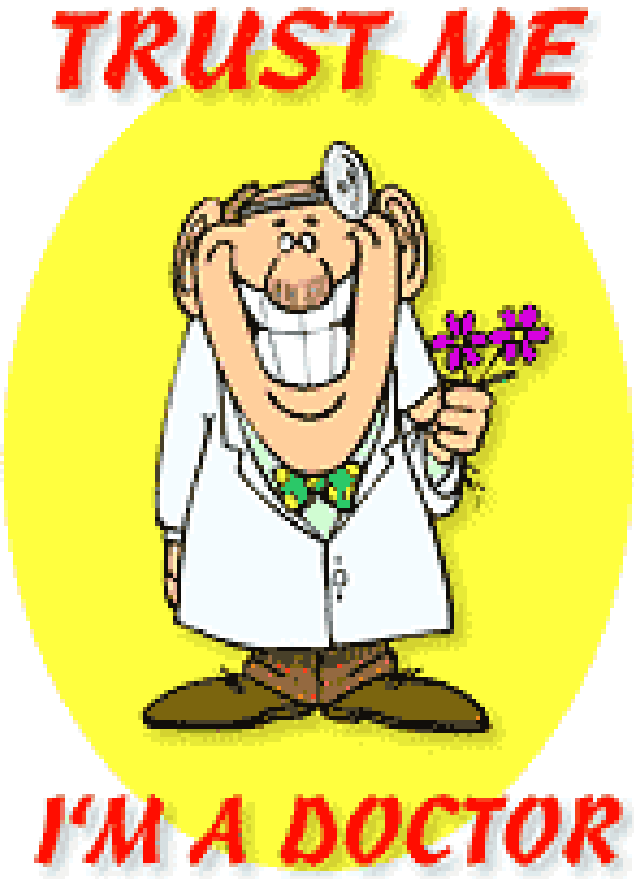
Top 3 Reasons for Recoupment of "Improper Payments" by the RAC

1. Services that did not meet Medicare's ***medical necessity*** criteria (e.g. therapy sessions that were excessive).
2. Services ***coded incorrectly*** (e.g. principal diagnosis on the claim did not match principal diagnosis on the medical records).
3. Failure to support claims with ***proper medical documentation*** (e.g. medical records did not describe adequately the procedures reported on the claim).

How to Establish Medical Necessity for Graftjacket # 1

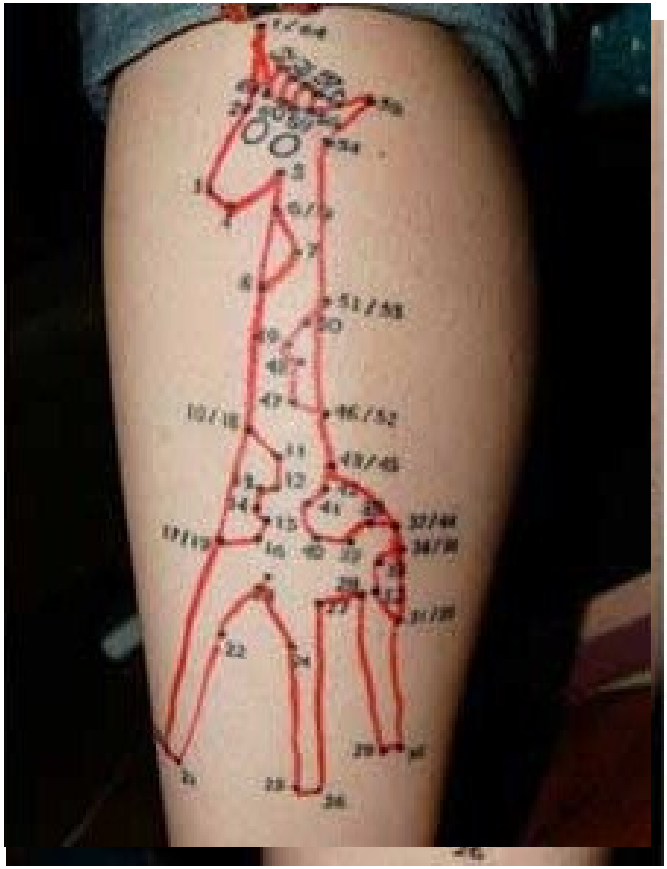
- 707.X related to Diabetes (280)
- Full thicknesss ulcer
- Apply Graftjacket

That was easy. What is wrong with that?
Will that sustain a RAC audit to demonstrate medical necessity?



Establishing Medical Necessity: Clinicians need to Connect the Dots

- Review the facts—describe the patient's history in light of the specific coverage policy requirements.
- Detail how ***THIS PARTICULAR PATIENT*** meets the coverage indication for Graftjacket by having failed 4 weeks of care **including** revascularization, infection control, nutrition control, off-loading.
- **Clinicians who fail to provide any of those >20 specific points can have to pay the money back (doctor and hospital)**



The "connect the dots" tattoo

Bioengineered Skin at Risk of Recoupment

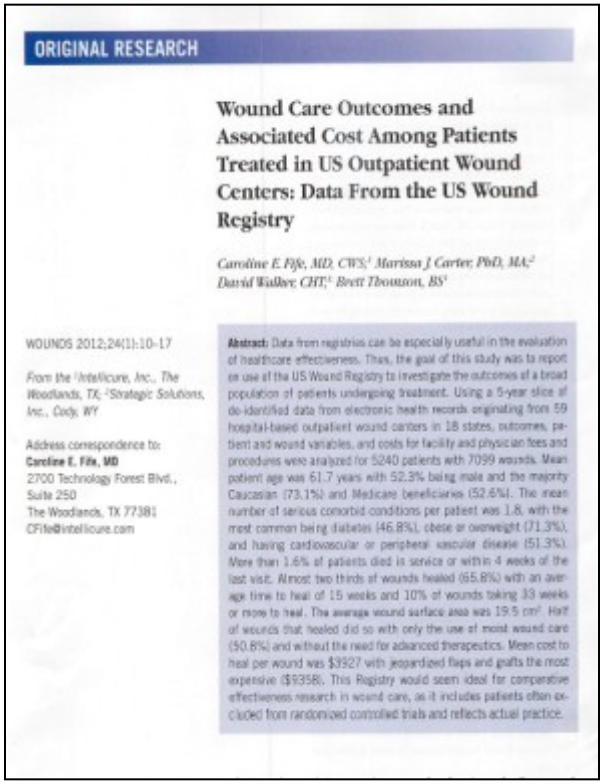
- Hospitals and doctors could have to pay this money back on post payment review if their documentation has not met ***their specific*** LCD requirements.
- You should familiarize yourself with the Graftjacket LCD in each region.

Rethinking Incentives

- Money is NOT the only driver product use.
- However, facilities can't afforc LOSE money on the product.
  - Other bioengineered skin optior have some economic advantage (more potential revenue per patient).
- In a VALUE based world, the most **effective** product will wi

Volume Based Payment Is Ending

- 5,240 outpatients with wounds accrued a total "cost to the system" of $29,249,500.
  - If we assume that 6.5 million people in the U.S. have VUs, PUs, and DFUs at any given time, then extrapolating our data would yield of a cost of at least ~ **$25 billion** to heal these wounds on the OUTPATIENT side.
- Medicare is going to turn off the ATM machine of outpatient wound care within 5 years.



ORIGINAL RESEARCH

Wound Care Outcomes and Associated Cost Among Patients Treated in US Outpatient Wound Centers: Data From the US Wound Registry

Caroline E. Fife, MD, CWS;[1] Marissa J. Carter, PhD, MA;[2] David Walker, CHT;[1] Brett Thomson, BS[1]

WOUNDS 2012;24(1):10-17

From the [1]Intellicure, Inc., The Woodlands, TX; [2]Strategic Solutions, Inc., Cody, WY

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Abstract: Data from registries can be especially useful in the evaluation of healthcare effectiveness. Thus, the goal of this study was to report on use of the US Wound Registry to investigate the outcomes of a broad population of patients undergoing treatment. Using a 5-year slice of de-identified data from electronic health records originating from 59 hospital-based outpatient wound centers in 18 states, outcomes, patient and wound variables, and costs for facility and physician fees and procedures were analyzed for 5240 patients with 7099 wounds. Mean patient age was 61.7 years with 52.3% being male and the majority Caucasian (73.1%) and Medicare beneficiaries (52.6%). The mean number of serious comorbid conditions per patient was 1.8, with the most common being diabetes (46.8%), obese or overweight (71.3%), and having cardiovascular or peripheral vascular disease (51.3%). More than 1.6% of patients died in service or within 4 weeks of the last visit. Almost two thirds of wounds healed (65.8%) with an average time to heal of 15 weeks and 10% of wounds taking 33 weeks or more to heal. The average wound surface area was 19.5 cm². Half of wounds that healed did so with only the use of moist wound care (50.8%) and without the need for advanced therapeutics. Mean cost to heal per wound was $3927 with jeopardized flaps and grafts the most expensive ($9358). This Registry would seem ideal for comparative effectiveness research in wound care, as it includes patients often excluded from randomized controlled trials and reflects actual practice.

Fife, CE, Carter MJ, Walker D, Thomson B. Wound Care Outcomes and Associated Cost Among Patients Treated in U.S. Outpatient Wound Centers: Data from the U.S. Wound Registry, Wounds 2012; 24(1) 10-17.

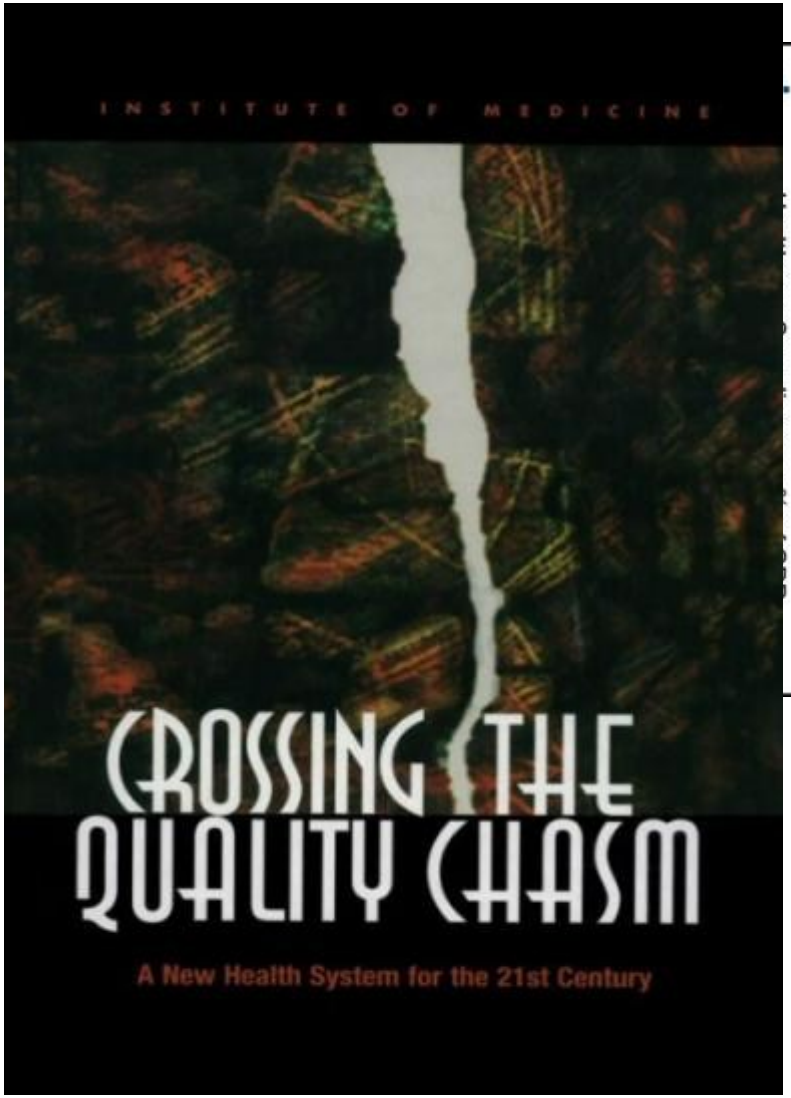
The Future of Medicare: A few billon Dollars poorer

- CMS has determined that outpatient "fee for service" as we know it will be gone in 3-5 years.
- Payment for doctors and hospitals will be based at least in part on whether "quality measures" are achieved.
- Future payment is likely to be bundled under an episode of care or via an ICD-9/10 diagnosis code with the doctor and the hospital paid together.

"Very soon you will be $25 BILLION dollars poorer

Moving from Volume to Value

- How can we reward physicians who provide efficient, cost effective care?
- As part of health care reform, CMS will shift from "paying for volume" to "paying for value."
  - "Fee for service" is dead because it rewards inefficiency
- Doctors and hospitals are going to be paid in LARGE part on the basis of patient ***outcomes***.



The Affordable Care Act (ACA) and "Value Based Payment"

- As part of the ACA, in 2015, a new **value-based payment modifier** will be used to provide *differential payments* to doctors **based on quality and cost of care.**
  - The payment adjustments are "budget neutral."
  - Some physicians will receive bonuses and some will be penalized
- Doctors who report will be paid with money taken from doctors who don't

Current PQRS Measures for Wound Care

1. Prescribe venous compression ONE TIME in a 12 month period
2. Patient education of diabetic foot care
3. NOT performing saline wet to dry dressings of a wound
4. NOT performing a wound swab culture
5. Prescription of diabetic foot ulcer off-loading.

We have 5 quality measures!

4/5 will not improve patient quality of care

Quality Measures, The Future of Healthcare

- All measures reporting will be electronic
  - They will ALL be reported directly from the electronic health record (EHR) using structured data (goodbye to free-text and dictation)
- The long range goal is to tie together resource use and cost in order to measure ***VALUE.***
- ***(Frankly this seems like a great opportunity for Grafjacket)***

Time is Running Out for the Wound Care Industry

- Wound care practitioners will be substantially harmed by not having sufficient measures to report.
- Wound care organizations and manufacturers must combine resources to create and test ***electronic measures***.
- With money and effort, we might get wound care quality measures ready by the start of value based purchasing (2015).

Time is running out for our industry