# Washington and Its Impact on Wound Care: Coding, Coverage and Payment Policies Through a Wound Care Lens

## Marcia Nusgart R.Ph.

Chief Executive Officer
Alliance of Wound Care Stakeholders





## Disclosures

None- receive membership fees from Alliance members







## Objectives

 Identify recent Medicare local coverage decisions that impact wound care clinicians

 Obtain an understanding of how recent Medicare initiatives relate to wound care

Understand the need for advocacy on wound care issues



## Alliance of Wound Care Stakeholders

#### The Alliance is ...

- The unified voice for the wound care community to advocate on public policy issues that may create barriers to patient access to treatments or care.
- Focused on key areas- appropriate coding, coverage and payment for wound care products and services,
   quality measures and wound care research
- A non-profit multidisciplinary trade association of physician specialty societies, clinical and non-clinical associations, patient organizations, wound care provider groups, wound care clinics and business entities
- The advocate-leveraging the expertise of its clinicians and clinical association members to influence regulatory agencies and decision makers

#### Mission of the Alliance is ...

- To promote quality care and access to wound care products and services for people with wounds
- To create a coverage, coding and payment environment supporting best practices and innovation in wound care





## Clinical Association Members

- Academy of Nutrition and Dietetics
- American Association of Nurse Practitioners
- American Board of Wound Medicine & Surgery
- American College of Foot & Ankle Surgeons
- American College of Hyperbaric Medicine
- American Diabetic Association Interest Group on
   Foot Care
- American Physical Therapy Association
- American Podiatric Medical Association
- American Professional Wound Care Association
- American Society of Plastic Surgeons

- American Vein and Lymphatic Society
- American Venous Forum
- Amputee Coalition
- Association for the Advancement of Wound Care
- National Lymphedema Network
- National Pressure Injury Advisory Panel
- Society for Vascular Medicine
- Society for Vascular Surgery
- Undersea & Hyperbaric Medical Society
- Visiting Nurse Associations of America
- Wound, Ostomy and Continence Nurses Society
- Wound Healing Society



The Alliance membership also includes business entities, nonclinical associations, wound care provider groups, wound care clinics, professional services firms.



## Focus of the Alliance- Advocacy!

Provide a unified wound care voice on policies, regulation & legislation

Defend and protect product categories important to wound care

Address threats to wound care practice

**Support wound care research** 





## Elections Matter: The U.S. Key Players

The White House

Congress

Department of Health & Human Services

Others









- Office of the President
- Office of Management and Budget

- House
- Senate
- Congressional Budget Office

- Office of the Secretary
- CMS Administrator
- (Medicare and Medicaid Programs)
- FDA Commissioner
- Medicare Administrative Contractors

- Medicare Payment Advisory Committee
- Government Accountability Office
- Office of the Inspector General
- Department of Justice
- Patient-Centered Outcomes Research Institute (PCORI)
- · Agency for Health Care Research and Quality (AHRQ)



#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES**

#### Chiquita Brooks-LaSure **ADMINISTRATOR**

Jonathan Blum PRINCIPAL DEPUTY ADMINISTRATOR & CHIEF OPERATING OFFICER

> Erin Richardson **CHIEF OF STAFF**

Karen Jackson **DEPUTY CHIEF OPERATING OFFICER** 

> EMERGENCY PREPAREDNESS **OPERATIONS** & RESPONSE OPERATIONS CAPT Skip A. Payne, Director Vacant, Dep. Dir. (FCM5

> > (FCM)

OFFICE OF INFORMATION TECHNOLOGY Rajiv Uppal, Dir. & CMS Chief Information Officer (CIO) OFFICE OF STRATEGY, PERFORMANCE, Bobby Saxon, Dep. Dir. AND RESULTS George Hoffmann, Dep. Dir. & Dep. CIO Bill Samples, Dir, George Linares, CMS Chief Technology Officer (FCMS)

> OFFICE OF SECURITY, FACILITIES AND LOGISTICS OPERATIONS James Weber, Director Elizabeth Mack, Dep. Dir. (FCMQ)

OFFICE OF HUMAN CAPITAL Tia Butler, Director & Chief Human Capital Officer Stephanie Bovell, Dep. Dir.

(FCMR)

APPROVED LEADERSHIP As of November 01, 2022

\*Acting

#### CENTER FOR CLINICAL STANDARDS AND QUALITY

Lee Fleisher, M.D., CMS Chief Medical Officer & Director Jean Moody-Williams, Dep. Dir. Jeneen Iwugo, Dep. Dir.

Shari Ling, M.D., CMS Dep. Chief Medical Officer Michelle Schreiber, M.D., Dep. Dir. for Quality & Value

> OFFICE OF CLINICIAN ENGAGEMENT Barry Marx, M.D., Dir.

> > (FCG)

(FCH)

CENTER FOR MEDICARE AND MEDICAID INNOVATION

Elizabeth Fowler, Deputy Administrator and Director Ellen Lukens, Dep. Dir. Arrah Tabe-Bedward, Dep. Dir. (FCP)

#### CENTER FOR MEDICARE

Dr. Meena Seshamani M.D. PhD, Deputy Administrator and Director Liz Richter, Dep. Dir. Cheri Rice, Dep. Dir.

#### CENTER FOR MEDICAID AND CHIP SERVICES

Daniel Tsai, Deputy Administrator and Director Anne Marie Costello, Dep. Dir. Sara Vitolo, Dep. Dir\* Dr. Aditi Mallick, Chief Medical Officer

#### CENTER FOR PROGRAM INTEGRITY

Dara Corrigan, Deputy Administrator and Director Bradley Hart, Dep. Dir. George Mills, Jr., Dep. Dir. (FCL

#### CENTER FOR CONSUMER INFORMATION AND INSURANCE OVERSIGHT

Dr. Ellen Montz Deputy Administrator and Director Jeff Grant, Dep. Dir. for Operations Jeff Wu,(he/him) Dep. Dir. for Policy Michael Jimenez, Center Chief Technology Office





OFFICE OF BURDEN REDUCTION & HEALTH INFORMATICS

Mary Greene, MD, Dir. Stella (Stace) Mandl, Dep. Dir.

OFFICE OF PROGRAM OPERATIONS &

LOCAL ENGAGEMENT

Nancy O'Connor, Dir

Erin Sutton, Dep. Dir. Of Drug Health Plan Opers.

Gregory Dill, Dep. Dir. For Innovation & Fin. Mgmt.

John Hammarlund, Dep. Dir. For Local Eng. & Admin Ray Hurd, Dep. Dir. For Strategy & Bus. Opers.

OFFICE OF ENTERPRISE DATA

AND ANALYTICS

Allison Oelschlaeger, Dir. & CMS Chief Data Officer

Andy Shatto, Dep. Dir.

OFFICE OF EQUAL OPPORTUNITY

AND CIVIL RIGHTS Anita Pinder, Director

Alaina Jenkins, Dep. Dir.

OFFICE OF COMMUNICATIONS

Bruce Alexander, Dir

Mary Wallace, Dep. Dir. for Operations

OFFICE OF LEGISLATION

Arielle Woronoff, Director

Jennifer Boulanger, Dep. Dir.

FEDERAL COORDINATED HEALTH

CARE OFFICE

Tim Engelhardt, Director Kerry Branick, Dep. Dir.

OFFICE OF MINORITY HEALTH

Dr. LaShawn McIver, Director

Capt. Wanda Finch, Dep. Dir.

Karen Aldana, Dep. Dir. for Communications<sub>(FCT)</sub>

(FCS)

(FCY)

(FCW

(FCA)

(FCC)

(FCQ)

(FCN)

DIGITAL SERVICE at CMS

(FCM3)

OFFICE OF ACQUISITION

AND GRANTS MANAGEMENT

Derrick Heard, Director

Douglas Bergevin, Dep. Dir.

OFFICES OF HEARINGS AND INQUIRIES

Randy Brauer, Director

James Slade, Dep. Dir.

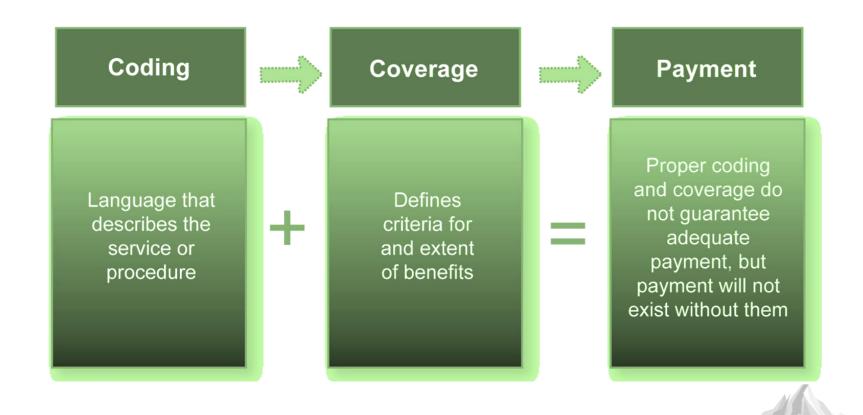
(FCMC)

(FCMN)

(FCME)

Andrea Fletcher, Director

# Foundations of Reimbursement: Mechanisms in the U.S.





## Examples of Coverage, Coding and Payment

- Coverage Policies
  - National Coverage Determinations (NCD) issued by CMS
    - o Examples: HBOT, pneumatic compression
  - Local Coverage Determinations (LCD) issued by CMS Contractors Medicare Administrative Contractors (MACs)
    - o Issued by A/B MACs (e.g., CTPs, debridement)
    - O Issued by DME MACs (surgical dressings, NPWT, pneumatic compression, support surfaces)
- Payment-fee schedules for physicians, Hospital outpatient, DMEPOS
- Billing codes known as HCPCS, CPT(procedures)



## What is a Local Coverage Determination(LCD)?

- Provides coverage, utilization, documentation, and other specific requirements
- Providers are required to adhere to all language in the policy
- If not, they will be required to pay the reimbursement back upon audit
- Each jurisdiction has a different policy with different requirements
- Public is afforded the opportunity to submit comments to impact the outcome of the policy
- All coverage criteria and medical policy information should be provided in



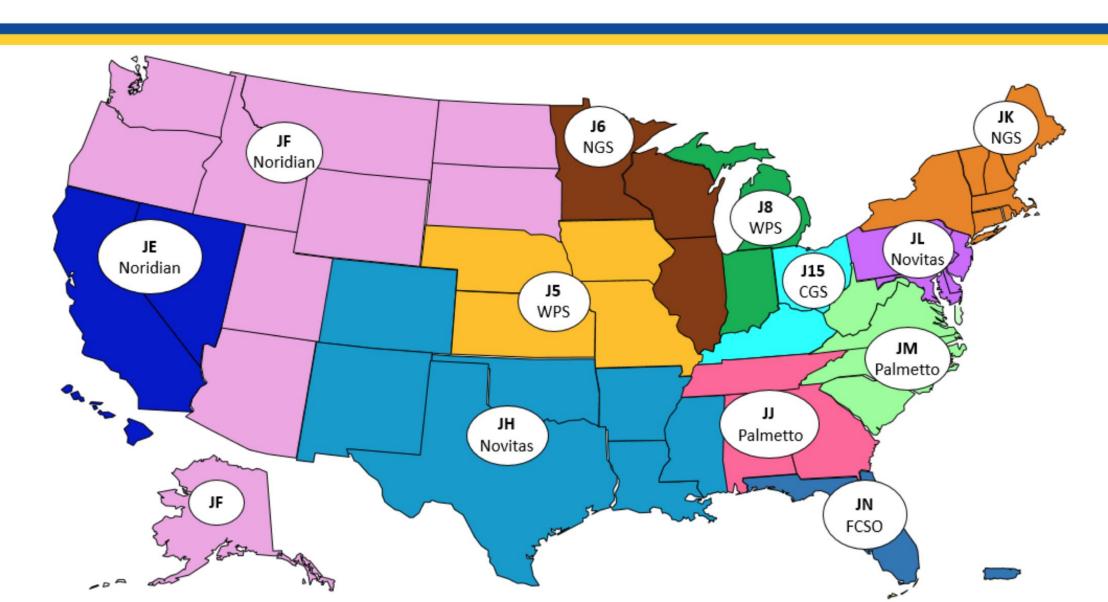
## What Is a Local Coverage Article (LCA)?

- Contains coding or other guidelines that complement an LCD
- 21<sup>st</sup> Century Cures clarified what is contained in a LCA
  - Clarification
  - Codes to be used for products or services contained in the LCD
- It is NOT meant to create coverage parameters
- Does not allow for a notice and comment period;

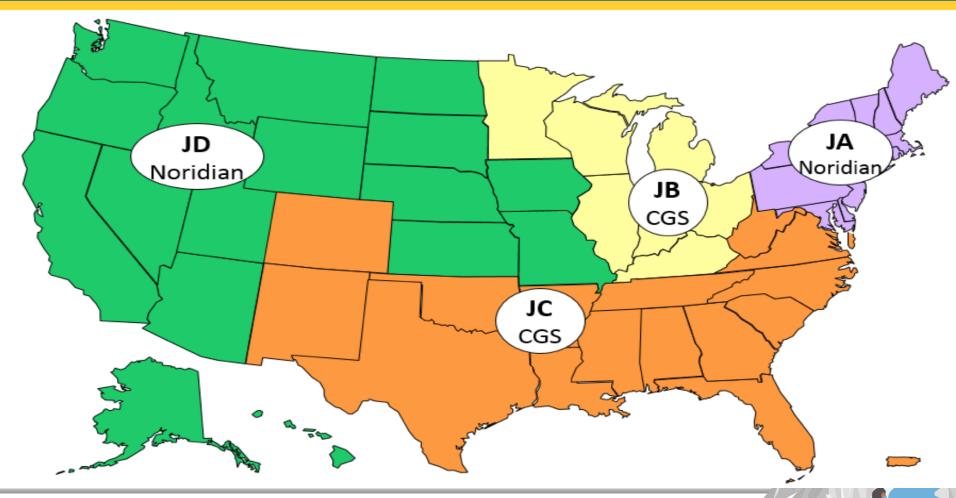




# A/B MAC Jurisdictions as of June 2021



# DME MAC Jurisdictions as of June 2021





## Advocacy and Impact: Unified Voice

## Provide a unified wound care voice on policies, regulation & legislation

#### **Advocacy Examples:**

- Comment Submissions to Regulatory Agencies and their contractors
- FDA Wound Healing Workshop
- Educational Sessions with CMS/PDAC/DMEMACs
- HCPCS Process Update
- Government Affairs-Lymphedema Treatment Act, Better Wound care at Home, Clinical Labor Coalition
- Health Equity Comments to CMS



















# Advocacy and Impact: Protection of Product Category

Defend and protect product categories important to wound care clinicians

#### **Advocacy Examples:**

Technology in Wound Care

- Preserve Coverage, Coding and Payment- CTPs
- Preserve Coverage- Silver and Antimicrobial Dressings
- Expand Coverage Alginate and Fiber Gelling Dressings
- FDA Convinced FDA to classify antimicrobial wound dressings as Class II with special controls









noridian









## Alliance Advocacy Activities: Coverage Issues

### Combat Restrictive Clinically Inaccurate LCDs/LCAs

- Novitas/First Coast- Skin Substitutes Treatment DFU/VLU- 2 draft policies-May and September
- Problems in the LCD:
  - Limitation of number of applications of CTPS in an episode is not supported by the clinical literature
  - CTPs Are NOT surgical supplies
  - Lack of evidence to support smoking cessation
  - Requirement that clinicians use the smallest package size available for purchase from the manufacturer
  - Inability for clinicians to be allowed to switch products as the wound progresses
  - Incorrectly describing the application of CTPs as an adjunct rather than an advanced therapy.
  - Lack of a consistent and accurate definition of a chronic non-healing ulcer





## Alliance Advocacy: Novitas/First Coast LCDs/LCAs

### Aggressively pursued their revision and their withdrawal by

- Providing oral testimony twice
- Submitting two sets of written comments
- Sending letter to parent company Guidewell and its CEO.
- Issues with the policy:
  - Objected to the shift of 40+ products from the covered to non-covered list,
  - Flagged numerous clinical inaccuracies
  - Not evidence based
- Current status: Final LCD/LCA will be released in Dec with substantial changes based on our advocacy.



## Alliance Advocacy: Coverage-CGS LCD/LCA

- CGS- Ohio/Kentucky -Skin Substitutes Treatment DFU/VLU
- LCD/LCA
- https://www.cms.gov/medicare-coveragedatabase/view/lcd.aspx?lcdid=39453&ver=10&contractorName=9&contract orNumber=228%7C2&proposedStatus=all&sortBy=title&bc=10
- . https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=59228&ver=7&bc=0
- Deadline Nov 19 to submit comments- Can submit comments through the website



# AAWC Members in Ohio/Kentucky-Need your help to submit comments to CGA!

### Some issues of concern in the LCDs/LCAs

- Many of statements and limitations in the LCD do not have the scientific evidence to support them
  - Example: Draft LCD permits 4 applications of a CTP; however, the literature cited in the LCD directly contradicts this limitation
- Utilization parameters seem arbitrary and will negatively impact patient care
- Conflicting, confusing and/or incorrect information
  - Incorrect: Draft LCD- "adequate glycemic control of hemoglobin AIC defined by this policy as <7% is recommended to reduce the incidence of DFUs and infections." We disagree with this statement clinically for chronic wound care patients as these patients can die when their A1C goes below 7%.
  - What is a chronic non-healing wound? Many definitions cited
- Significant procedural issues- CGS did not include any clinical stakeholders- including convening a meeting of its CAC in advance of writing the LCD and LCA— Usually the CAC will answer key questions posed by the medical directors and discuss the evidence





## Alliance Advocacy: Payment Issues

#### Protect Patient Access to CTPs in Physician Office and HOPPS

• Alliance conducts 2 meetings with CMS Senior staff (1) to address unintended payment aspects under current coding policies- March (2) Educational seminar on CTPs

### **Physician Fee Schedule PPS Rule**

- Alliance CMS comments to CMS --proposal to reclassify all CTPs as "supplies incident to a lead physician service" and package payment into practice expenses would create barriers to care that could ultimately to increased infections and amputations. Urged CMS to remove or delay the proposed CTP provisions until patient access issues could be further studied and vetted with key stakeholders.
- **HUGE ADVOCACY WIN:** Following tenacious advocacy, these highly problematic provisions were NOT moved forward in the final 2023 PFS and the Agency announced plans to convene a public meeting on these issue in early 2023.





## Alliance Advocacy: Payment Issues

# Protect Patient Access to CTPs in Physician Office and HOPPS

### **Hospital Outpatient PPS Rule**

Technology in Wound Care

- The Alliance recommended policy updates to enable PBDs to
  - (1) be reimbursed for an adequate amount of CTP products for larger wounds so that they do not need to absorb the cost themselves or refer patients out,
  - (2) to equalize the payment for CTP application for wounds/ulcers of the same size no matter the anatomic location, as PBDs are currently reimbursed at different levels depending on wound location.
- Update: While the Agency did not include these policy adjustments in the final 2023 HOPPS, we will continue to elevate these issues moving forward

## Advocacy and Impact: Research

- 1. Created Alliance Wound Care Evidence Summit May 2022
- 2. Address perceived lack of wound care evidence and value of wound care
- 3. Explore solutions to address limitations in wound care evidence-base

#### **Examples:**

- "An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds" (2017 Value in Health)
- "Harnessing Big Data for Wound Healing Research" (2016 ISPOR presentation)
- "Consensus Principles for Wound Care Research Obtained Using a Delphi Process" (the "POWER" paper, 2012)





An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds



Samuel R. Nussbaum, MD¹, Marissa J. Carter, PhD, MA², Caroline E. Fife, MD³,4,5, Joan DaVanzo, PhD, MSW6, Randall Haught6, Marcia Nusgart, RPh7,\*, Donna Cartwright, MPA®

<sup>3</sup>Schaeffer Center for Health Policy and Economics, University of Southern California, Los Angeles, CA, USA; <sup>2</sup>Strategic Solutions, Inc., Cody, WY, USA; <sup>2</sup>Baylor College of Medicine, Houston, TX, USA; <sup>3</sup>CHI St. Lukes Hospital, The Woodlands, TX, USA; <sup>3</sup>The US Wound Registry, The Woodlands, TX, USA; <sup>3</sup>Dobson/DaVanzo & Associates LLC, Vienna, VA, USA; <sup>3</sup>Alliance of Wound Care Stakeholders, Bethesda, MD, USA; <sup>3</sup>Integra Infectiences, Plainsboro, NJ, USA

ABSTRACT

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, 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. 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 vere for surgical wounds (\$11.7, \$13.1, and \$38.3 billion), followed by

diabetic foot ulcers (86.2, \$6.9, and \$18.7 billion.). The highest cost estimates in regard to site of service were for hospital outpatients (\$9.9-\$53.8 billion), followed by hospital inpatients (\$5.0-\$24.3 billion). 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.

Keywords: Medicare 5% Limited Data Set, Medicare spending, prevalence of wounds, wound care.

Copyright © 2018, International Society for Pharmacoeconomics and Outcomes Research (ISPOR). Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license



https://www.valueinhealthjournal.com/article/S1098-3015(17)30329-7/fulltext?\_returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS1098301517303297%3Fshowall%3Dtrue



## How To Stay Informed and Be Involved-Resources





## Best Ways to Stay Informed and Be Involved!

Register for the Listserv for your local Medicare Administrative Contractor and sign up to attend its webinars and teleconferences (on their websites!)

Sign up to receive updates on and participate in CMS policyrelated material

Be active in AAWC!





## Resources

- CMS Listserv
- A/B MAC websites
- DME MAC websites
- Alliance websitewww.woundcarestakeholders.org





## CMS Listservs

- Can Sign up for CMS Listservs in bottom right hand corner of any page on CMS.gov
  - Open door forums physician/nurse/allied health professions; home health/hospice/DME; nurses; SNF <a href="https://public.govdelivery.com/accounts/USCMS/subscriber/new?category\_id=USCMS\_C115">https://public.govdelivery.com/accounts/USCMS/subscriber/new?category\_id=USCMS\_C115</a>
  - MLN Connects https://public.govdelivery.com/accounts/USCMS/subscriber/new? pop=t&topic\_id=USCMS\_7819
  - CMS coverage email





## A/B MAC Contact Information

- Cigna Government Services (CGS) <a href="https://www.cgsmedicare.com/partb/">https://www.cgsmedicare.com/partb/</a>
- First Coast Service Options Inc.(FCSO) <a href="https://medicare.fcso.com">https://medicare.fcso.com</a>
- National Government Services (NGS) <a href="https://ngsmedicare.com">https://ngsmedicare.com</a>
- Noridian-
  - JE: <a href="https://med.noridianmedicare.com/web/jeb">https://med.noridianmedicare.com/web/jeb</a>
  - JF: <a href="https://med.noridianmedicare.com/web/jfb">https://med.noridianmedicare.com/web/jfb</a>





## A/B MAC Contact Information (cont'd)

#### Novitas

- JH: <a href="https://www.novitas-solutions.com/webcenter/portal/MedicareJH">https://www.novitas-solutions.com/webcenter/portal/MedicareJH</a>
- JL: <a href="https://www.novitas-solutions.com/webcenter/portal/MedicareJL">https://www.novitas-solutions.com/webcenter/portal/MedicareJL</a>

#### Palmetto

- JJ: https://www.palmettogba.com/palmetto/providers.nsf/DocsCatH/JJ%20Part%20B
- JM: https://www.palmettogba.com/palmetto/providers.nsf/DocsCatHome/JM%20Part%20B

#### WPS J5 and J8:

https://www.wpsgha.com/wps/portal/mac/site/home





## DME MAC Contact Information

- Jurisdiction A and D Noridian
  - https://med.noridianmedicare.com

- Jurisdiction B and C CGS
  - https://cgsmedicare.com





## Questions? Contact information

Marcia Nusgart R.Ph.

marcia@woundcarestakeholders.org

