

# **Presentation to the Medicare Advisory Panel on Hospital Outpatient Payment:**

## **OPPS Packaging Policy for MIST Ultrasound Therapy (CPT 97610)**

**Spring 2016 Meeting**

# Summary of Presentation

- **Presenters:** Dr. Gary Gibbons, MD FACS; Eric Greig, Latham & Watkins LLP\*
- **CPT Code Involved:** 97610
- **APC Affected:** 5051
- **Description of the issue:** MIST Therapy, described by CPT code 97610, is a primary, independent procedure indicated to promote wound healing. For the years prior to January 1, 2016, code 97610 was assigned status indicator "T" to properly indicate that fact. For 2016, CMS created a new skin procedure APC, 5051, and assigned status indicator "Q1" to code 97610, designating the procedure as "ancillary" and conditionally packaging reimbursement for the service with S, T, or V procedures.
- **Clinical Description of the Service:** The MIST Therapy procedure is a non-contact, low-frequency, low-intensity ultrasound treatment delivered through a saline mist to the wound bed.
- **Recommendation and Rationale:** We recommend that CMS return code 97610 to status indicator "T" rather than "Q1" because it is an independent procedure with unique clinical effects supported through numerous published studies.
- **Potential consequences of not making the change:** By packaging reimbursement for 97610 into payment for other, unrelated procedures, CMS fails to recognize the independent nature of MIST Therapy and the expense of the equipment and practitioner time required to perform the procedure, resulting in limited access to this proven wound-healing procedure for Medicare beneficiaries in the outpatient setting.

\*Dr. Gibbons does not have an existing financial relationship with Alliqua Biomedical and is not being compensated for his participation in this presentation. Eric Greig is an attorney representing Alliqua Biomedical, Inc., the manufacturer of the MIST Therapy System.

# What is MIST Therapy?

- Non-contact, low-frequency, low-intensity ultrasound (NLFU) delivered through a saline mist to the wound bed
- Ultrasound stimulates cells within and below the wound bed to accelerate healing
- Only noncontact ultrasound cleared by FDA with an indication to promote wound healing
- CPT code 97610 descriptor is specific to MIST Therapy and includes not only the NLFU therapy itself, but also wound assessment and instructions for ongoing care

# Low-frequency Ultrasound Equipment

- **Treatment Wand** vibrates over 40,000 times per second to create low-frequency sound waves
- **Applicator** attaches over the wand and dispenses saline, which is the conduit to deliver the sound waves to the wound bed
- **Ultrasound Generator** produces the energy required by the treatment wand and provides a constant delivery of saline while the ultrasound is being delivered

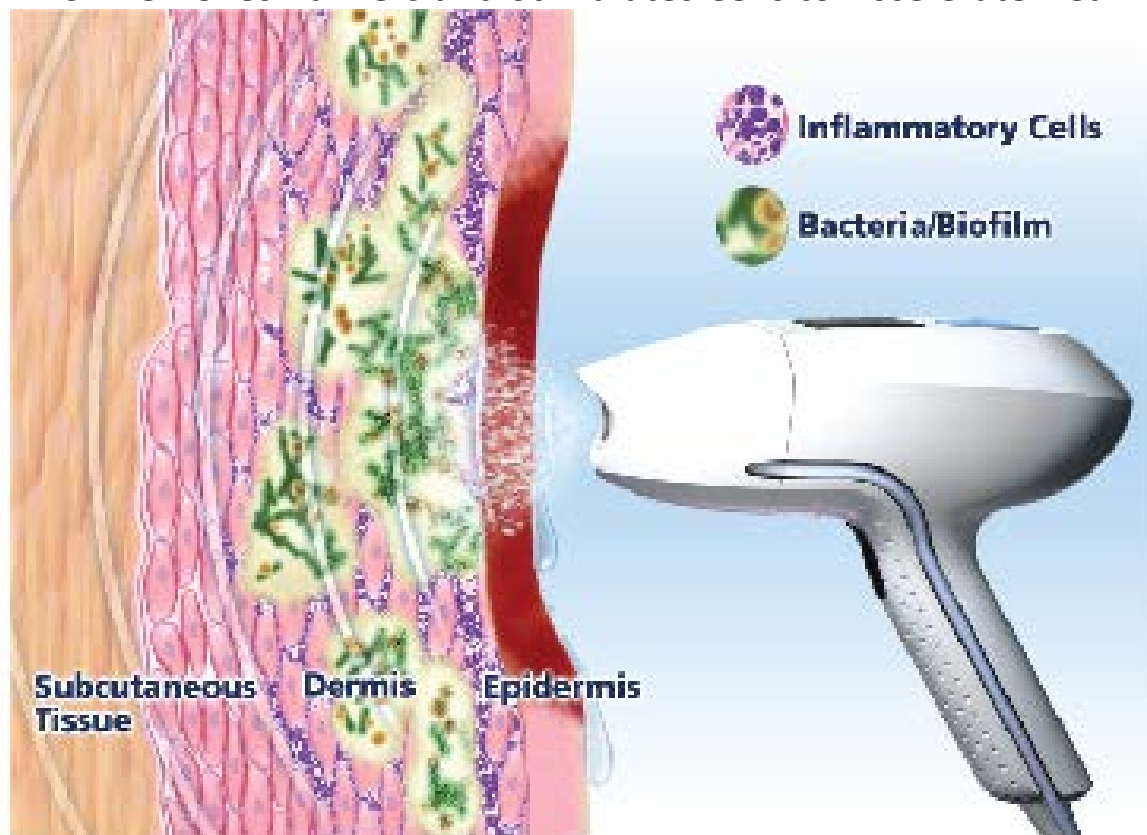


# Independent Procedure

- MIST Therapy is a primary, independent procedure that should not be considered an “ancillary” procedure under the OPPS packaging policy
- American Medical Association (AMA) *CPT Assistant* (June 2014) describing CPT 97610:
  - AMA states that debridement and MIST Therapy ***“represent different interventions using different medical equipment with distinctly different clinical objectives.”***
  - Continuous attendance by a qualified healthcare practitioner is required

# MIST Therapy

## MIST Removes Barriers and Stimulates Cells to Accelerate Healing

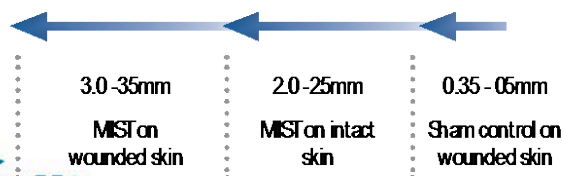


## Stimulates Cells to Promote Healing

- Increased blood flow through vasodilation
- Increased angiogenesis
- Early release of growth factors
- Increased collagen deposition

## Removes Barriers to Healing

- Reduces a wide-range of bacteria
- Disrupts biofilm
- Reduces sustained inflammation
- Reduces MMP-9



# Clinical Applications of MIST Therapy

- Wounds not responsive to evidence-based standard of care that need help transitioning to the proliferative stage following early aggressive surgical debridement
- Painful wounds or painful debridement procedures
- Deep tissue injury (DTI)



# Coding and OPPS Payment Policy

- NLFU Therapy was described by CPT code 0183T prior to 2014
  - Assigned status indicator “T” to indicate a separately payable service under OPPS
- Category I CPT code 97610 established in 2014
  - Code was assigned “T” status indicator in 2014
  - CMS’s 2015 reassessment of packaging policy for ancillary and primary services again confirmed 97610 as a separately payable, primary procedure
- CMS reversed course in 2016, assigning 97610 a status indicator of “Q1” to conditionally package the procedure as an ancillary procedure into other STV procedures



# OPPS Packaging Considerations

**MIST Therapy does not meet any of the Medicare OPPS criteria to be considered an “ancillary” procedure subject to the packaging policy.**

- MIST Therapy is an independent procedure, not typically supportive, dependent, or adjunctive to another procedure
- Geometric mean cost exceeds the packaging cost threshold
- Claims data shows 97610 is not typically performed with a primary procedure

# OPPS Packaging Considerations (cont'd)

**MIST Therapy does not meet any of the Medicare OPPS criteria to be considered an “ancillary” procedure subject to the packaging policy.**

- AMA’s CPT description for 97610 supports the primary nature of the procedure
- Practitioner time devoted to MIST Therapy indicates an independent procedure

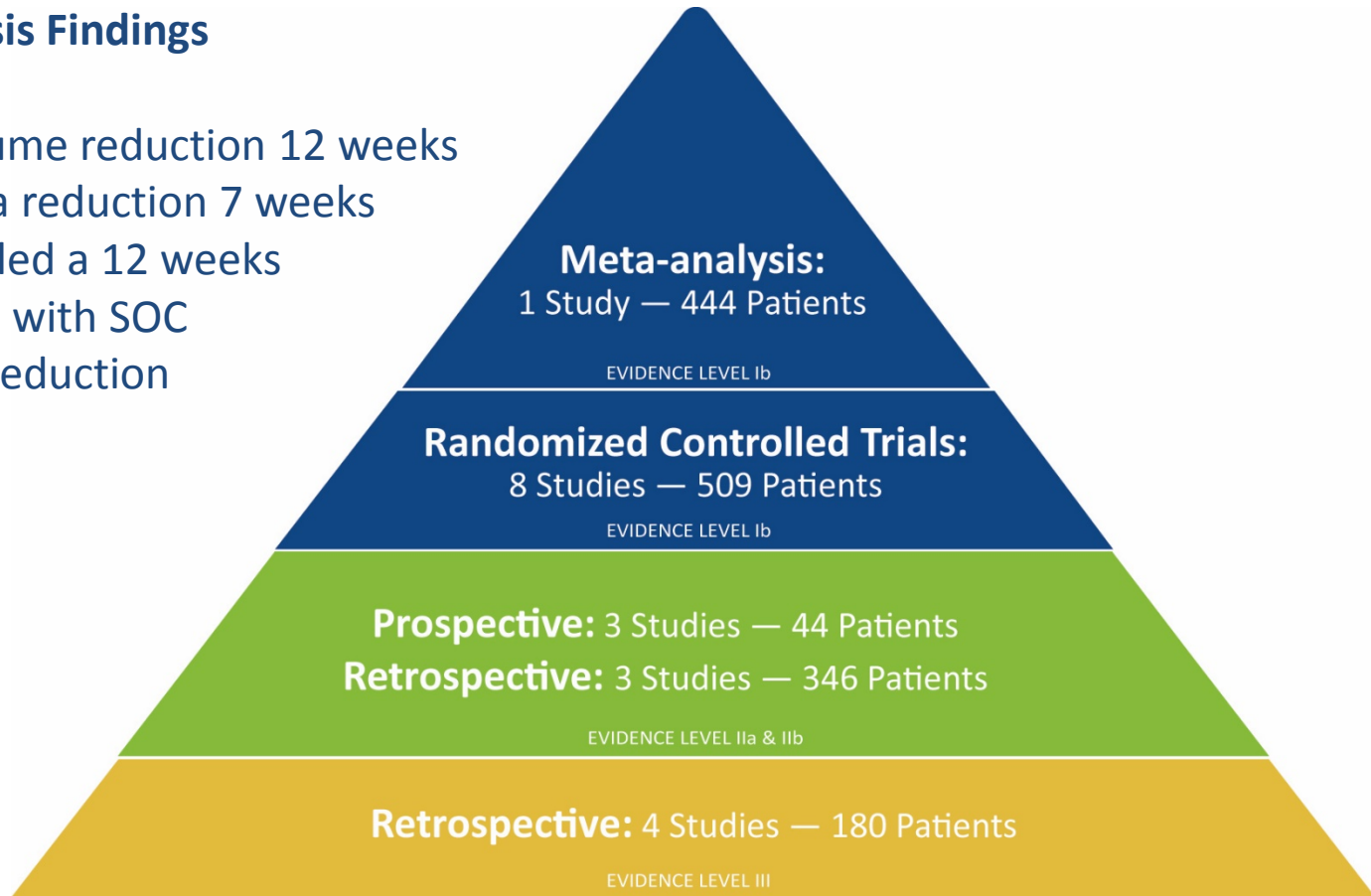
**All considerations support reversal of the 2016 status indicator assignment of “Q1” and a return to status indicator “T” for MIST Therapy’s CPT code 97610.**

# Addendum

# Summary of MIST Therapy Clinical Evidence

## Meta-analysis Findings

- 79.7% volume reduction 12 weeks
- 85.2% area reduction 7 weeks
- 41.7% healed a 12 weeks
  - vs. 24% with SOC
- 79% pain reduction



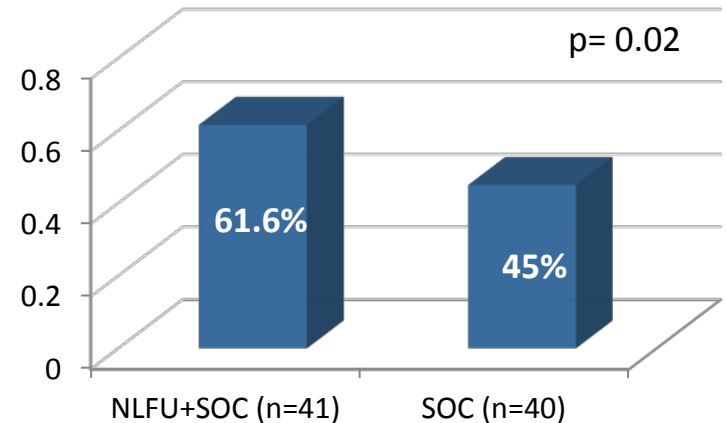
# Recent Clinical Data-INBALANCE VLU

- Prospective RCT, 22 centers, 112 subjects eligible, 81 randomized and treated
- Treatment arms: MIST + SOC (3x/week) versus SOC (1x/week minimum)

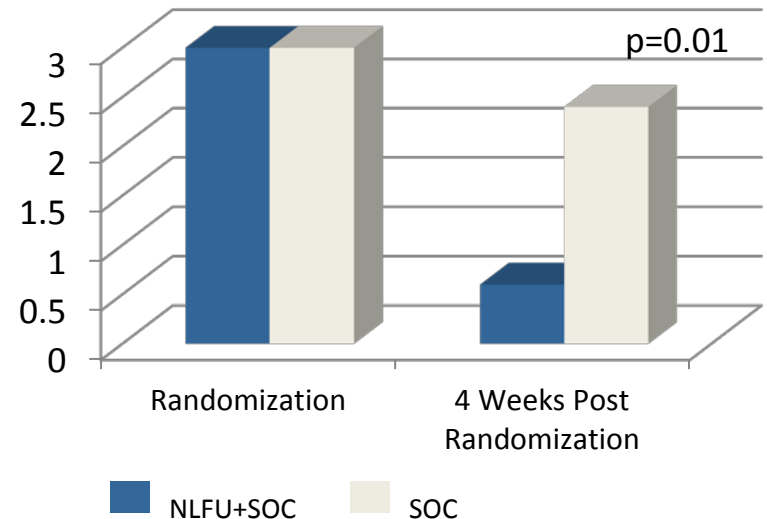
## Results

- Analysis cohort N=81 (MIST 41, SOC 40)
- Primary endpoint - % wound area reduction at 4 weeks post randomization
  - Mean % wound area reduction 61.6% MIST vs, 45% SOC,  $p=0.02$
  - Median % wound area reduction 65.7% MIST vs SOC 44%,  $p=0.02$
  - Actual mean change in wound area reduction 9.0cm<sup>2</sup> MIST vs. 4.1cm<sup>2</sup> SOC,  $p= 0.003$
- Pain reduction –MIST 80% , SOC 20%  $p=0.01$

4 Week Wound Area Reduction



VAS Pain Assessment



# Description of Procedure

## AMA CPT Assistant (2014) for 97610:

1. The patient is appropriately positioned for wound evaluation and treatment. A water-resistant drape is placed under the area of treatment. After careful wound assessment, measurement, and photography, the wound and surrounding tissue are cleansed. The equipment and supplies required for low-frequency ultrasound (LFU) therapy are prepared. LFU is delivered to the patient by the qualified health care professional by holding the transducer and applicator 1 cm to 1.5 cm away from the wound bed and moving the applicator in a serpentine fashion along the entire wound and wound margin for the designated time, based on the wound size. At the conclusion of the LFU treatment, the wound bed is wiped with gauze, the wound bed and surrounding tissue are assessed for clinical changes, and the appropriate dressing is applied.