Appealing Denied Claims

To raise payer awareness of the demand for MIST Therapy® and its effectiveness, Celleration recommends that healthcare providers appeal every denied claim.

Your first step in preparing an appeal is to contact the Celleration Reimbursement Hotline at (866) 307-MIST, Option 3.

Appealing Denied Claims

Like appeals of Prior Authorization requests, appeals of denied claims have the potential to change a payer's behavior. Appeals demonstrate a demand for MIST Therapy from you, the clinician, by showing the payer that you and your patients want MIST Therapy. Appeals generally are reviewed at a higher level within the payer organization. Payers that are forced to review large number of appeals will reevaluate their non-coverage of MIST Therapy because appeals are a costly administrative expense.

Submit an appeal even if the payer has a non-coverage statement about MIST Therapy. You may be surprised to learn that between 40%-50% of denied claims are overturned on appeal.

Keep in mind that you are appealing not a single MIST Therapy treatment, but usually several treatments over the course of the patient's wound care. With help from Celleration, minimal time is required for you to prepare and mail the appeal.

Starting the Appeal

The first step in preparing the appeal is to contact the Celleration Reimbursement Hotline at (866) 307-MIST, Option 3.

With Medicare or commercial payers, the Remittance or Explanation of Benefits (EOB) will provide a denial reason and your appeal options.

Some possible denial reasons include:

- CPT 0183T was denied as a bundled service (Correct Coding edits)
- CPT 0183T was not recognized as a valid code
- MIST Therapy was denied as not medically necessary, experimental, investigational, or unproven
- Documentation was required before the claim can be processed

By supplying Celleration the Remittance/EOB, we can better support your appeal. Celleration does not need any confidential patient information. Blacken out the patient identifiers to retain patient confidentiality.

Celleration tracks payer coverage and non-coverage across the United States and can tell you if a particular payer has reimbursed for MIST Therapy.

Celleration will send you specific information to include in your appeal:

- Cut-and-paste language for your appeal letter, based on the denial reason
- Suggested information for the prescribing physician's Letter of Medical Necessity (LMN), if required by the payer
- Therapy Summary of noncontact, non-thermal low frequency ultrasound
- Summary of published, peer-reviewed studies with bibliography

Involve Your Patient

Encourage your patients to advocate for themselves. Patients should contact their insurance company and their employer when a claim is denied. Many large employers are self-insured, meaning the employer ultimately decides whether to pay a claim. Patient advocacy information is available upon request from your Celleration representative or reimbursement@celleration.com.

Appealing Denied Claims

Medicare Claim Appeals

Traditional, fee-for-service Medicare has a specific appeals process with timely filing requirements:

- Redetermination is the first level of appeal. Any dollar amount can be appealed and must be submitted within 120 days from the date initial claim decision (i.e., Remittance) was received.
- Reconsideration is the second level of appeal. These are reviewed by the Medicare QIC — Qualified Independent Contractor. Any dollar amount can be appealed and must be submitted within 180 days from the date of the Redetermination decision.
- Administrative Law Judge (ALJ) Hearing is the third level of appeal. These are very effective forums for receiving an unbiased, patient-focused hearing on why MIST Therapy was reasonable and necessary wound care for your patient. Requests for an ALJ Hearing must be submitted within 60 days from the date of the Reconsideration decision.

Sample Letter of Medical Necessity

Your letter of medical necessity should include the following elements:

- Wound history (e.g., diagnosis and onset date)
- Wound characteristics (e.g., initial wound size versus current wound size)
- A description of the wound (e.g., location, necrosis, tunneling, signs of infection)
- Patient's response to previous wound treatments (e.g., lack of progression to wound healing or lack of complete wound healing)
- The reason(s) that low frequency, noncontact non-thermal ultrasound (LFUS) is requested, and the expected outcome using LFUS:
  - LFUS promotes wound healing
  - LFUS is reported in multiple publications to accelerate wound closure compared to standard wound care treatments
  - Patient had a painful wound, and/or other interventions to treat the wound caused severe pain. Non-contact LFUS offers the patient a painless wound care procedure
  - Necrotic tissue/slough was present and LFUS removes yellow slough and exudates
  - Inflammation and swelling of patient's wound could indicate that an infection was present and LFUS removes bacteria
  - Infected wound was found via culture or punch biopsy, LFUS was prescribed because it removes bacteria
- Explanation that the effectiveness of LFUS therapy for this patient may be evident relatively quickly, and that LFUS would be stopped if the wound is not progressing.
- Conclude with a clear request for approval of LFUS for this patient's wound over a specified period (i.e., up to 12 treatments in the first 30 days).

Payer Name
Attn: Claim Appeals
Address
City, ST ZIP

RE: Appeal of Denied Claim for patient Jane Doe, subscriber ID XXXXXXXXX

This letter appeals the denial of the attached claim for wound care services provided by American Medical Center for the above-referenced patient.

The treatment provided — low frequency, noncontact, non-thermal ultrasound CPT 0183T — is an appropriate modality for this patient, and has been shown in published, peer-reviewed literature to have a healing affect on venous leg ulcers. Published, peer-reviewed studies of low frequency, noncontact, non-thermal ultrasound demonstrates the following:

- Reduce wound area and volume
- Close (or heal) more wounds compared to standard wound care
- Reduce the time needed to heal wounds

A summary of the published, peer-reviewed studies and full bibliography is enclosed for your review.

The devices used to perform CPT 0183T are FDA cleared and are not investigational. The FDA labeling for the devices reads that the device "produces a low energy ultrasound-generated mist used to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue exudates and bacteria."

This patient's wound has been present for three (3) months and had not healed with prior treatments. Low frequency ultrasound was used on this patient because:

- It promotes wound healing
- Patient had a painful wound and other interventions to treat wound caused severe pain. Non-contact LFUS offered the patient a painless wound care procedure.
- Wound volume had not improved with previous treatments, and low frequency ultrasound is reported in multiple publications to accelerate wound closure compared to standard wound care treatments.
- Necrotic tissue/slough was present and low frequency ultrasound removes yellow slough and exudates.
- Inflammation and swelling of this patient's wound indicated a probable infection, and I performed this treatment because it removes bacteria.

I would appreciate the opportunity to have a discussion with your Medical Director about this denied claim, to explain my experience with low frequency ultrasound, the outcomes I have seen, the patient selection criteria for using this treatment, and the published evidence supporting its efficacy.

Sincerely,
Name, Credentials
Phone Number

See page 3D of this document for an example of a Letter of Medical Necessity.

For an electronic version of this letter that you can customize and send to payers, please contact reimbursement@celleration.com

Frequently Asked Questions

I received a claim denial. What should I do next?

Please contact the Celleration Reimbursement Hotline at (866) 307-MIST, Option 3 or send an email to reimbursement@celleration.com. We will assist you with the steps and documentation needed to overturn the denial.

Will it take a long time to prepare the appeal?

No. Celleration will provide you documentation for your appeal based on the reason for the denial. Information specific to the patient (which you likely already have in the patient's file) should accompany the MIST Therapy / CPT 0183T evidence. Simply combine these pieces and mail to the payer.

Is it worth it to appeal the denial? It was only for one MIST Therapy treatment.

Yes, for a number of reasons. First, the easiest thing for a payer to do is deny a claim, especially on the basis of "new and experimental." Appealing a claim denial gets the attention of a higher level clinician who reviews the MIST Therapy evidence, patient history, and medical necessity. Second, appealing claim denials is a "grass roots" effort to change payer coverage policy. With enough appeals and overturning of denied claims, payers will revise their coverage policy. Finally, you are appealing not a single MIST Therapy treatment, but usually several treatments over the course of the patient's wound care.

How often do payers overturn their original denials?

Very often. In 2006, America's Health Insurance Plans reported that ~40% of appeals are overturned. A 2007 report from the New York Insurance Department reported that over 46% of appeals are overturned.

Can I ask the patient to submit the appeal?

If the payer requires the patient to submit the appeal, then please inform your patient. Your patient may call the Celleration Reimbursement Hotline at (866) 307-MIST, Option 3 for help in preparing the appeal. Patient appeals can be very compelling to a payer and to the patient's employer, especially when that employer is a "self-insured" group.

What is a "self-insured" employer?

Many large employers are self-funded or self-insured, meaning the employer ultimately pays for the medical care of its employees and their covered dependents. The insurance company only acts as an administrator by providing a preferred network of healthcare providers and processing claims. Patients with a "self-insured" employer should contact their benefits manager, with Celleration's assistance, to explain their desire to receive MIST Therapy for their non-healing wound.

What should I send to the payer with my appeal?

Please refer to the "Starting the Appeal" section on page 3A of this document. Celleration will provide you customized, electronic documents to appeal the claim based on the denial reason.

How do I appeal a Medicare denial?

Medicare has three steps for appealing any denial, including a denial based on a Medicare contractor's non-coverage policy. Each step must be followed in sequence and has deadlines for submitting the appeal. Please see page 3B for more information on "Medicare Claim Appeals".

CPT 0183T was denied as "investigational." How should we appeal that claim denial?

Both CPT 0183T and MIST Therapy are not experimental. MIST Therapy was cleared by the FDA in 2004, is supported by over 20 peer-reviewed published articles, and has been used in clinical practices in more than 35,000 patients in over 800 locations throughout the United States. Both the AMA and CMS (Medicare) write that codes like CPT 0183T are not investigational or experimental. The Celleration Reimbursement Hotline can provide you an electronic document to use in explaining this to the payer.

EXAMPLE LETTER OF MEDICAL NECESSITY

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Address
City, ST ZIP

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Sincerely,
Name, Credentials
Phone Number

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