

August 1, 2006

Dear Sirs,

As an employee of a MEDICAL CENTER REHABILITATION DEPARTMENT in Panama City, Florida we see quite a number of Medicare patients who have problems with neuropathy and have benefited a great deal from our Anodyne Program.

It seems to me that the elderly population keep losing benefits that they truly need.

This program has had a significant positive result with our patients and I would urge whomever can change this "Non-Coverage Draft Policy for Infrared Therapy and Devices" to reconsider this irrational decision.

People are driving motor vehicles and walking with little to no feeling in their feet...this makes this a national danger issue in my mind and if Anodyne Therapy returns feeling to feet and other limbs I feel that this treatment is really quite necessary for everyone's safety.

I know you are going to say "well, if they have no feeling in their feet they shouldn't be driving" how do you even know if the person passing you on the highway has feeling in their feet.....do you want to take that chance? I don't.

Please reconsider discontinuation of re-imburement for Anodyne Therapy. It is a necessary and positive therapy for anyone with neuropathy.

Thank you,

A Concerned Citizen and Medical Employee

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Please reconsider discontinuation of re-imburement for Anodyne Therapy. It is a necessary and positive therapy for anyone with neuropathy.

Thank you,

A Concerned Citizen and Medical Employee

CARROLL COUNTY MEMORIAL HOSPITAL
Rehab Department
1502 North Jefferson
Carrollton, MO 64633
660-542-1664

8/08/06

MEDICARE NCD Comments

Dear Sirs:

I am writing concerning the proposed non-coverage policy for Anodyne Therapy and Anodyne Home Systems. As a licensed physical therapist, I have found that Anodyne Therapy has been extremely successful in treating diabetic neuropathy by producing improved sensation and decreased pain allowing better range of motion and gait. These patients that have received Anodyne Therapy have become safer ambulators, more active people and overall achieve a better level of health than prior to the Anodyne treatment.

We have been extremely pleased with the outcome of the Anodyne product and we have case studies that we can produce concerning the outcome and the reduction of pain. Most out patients would not be inclined to involve themselves with a home unit if they did not feel that they needed it.

Please reconsider the proposal for non-coverage for infrared therapy because it has been instrumental in pain control and improvement in patient function.

Sincerely,

Mady Duden PT



"Clinical Nutrition by Health Professionals"

Attention: Medicare NCD Comments
Anodyne Therapy, LLC
13570 Wright Circle
Tampa, FL 33626

To Whom It May Concern:

Our Clinic has been using anodyne therapy for a year and half and has had excellent results with this therapy. We have seen patients with Polly-neuropathy, diabetic neuropathy, and circulatory problems to the lower extremities. All of our cases, except two, have made excellent recovery. We have also followed up in six-month integrals after the patient has been released, and our feedback has been excellent. There has also been decreased pain, improved sensation, and improvement in activities of daily living. Patient's safety, which is of utmost importance, is excellent we have had absolutely no problems during our treatment time.

In my opinion I think none coverage by Medicare will drastically reduce access to this appropriate care for these patients. As a practitioner in the field I strongly recommend continued coverage by Medicare.

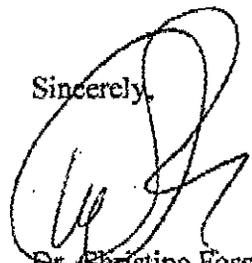
Sincerely,

James V. Gallo
James V. Gallo

Attn: Medicare NCD
Comments
Anodyne Therapy, LLC
13570 Wright Circle
Tampa, FL 33626

To Whom It May Concern:

I am writing to you regarding the Non-Coverage Draft Policy for Infrared Therapy devices. We have used the anodyne therapy in our office for many years. We have treated over 100 patients who have exhibited neuropathic symptoms. There have been clinical outcomes of increased sensation, decreased pain, and improved activities of daily living. Patients have not experience any side effects during treatment. We are asking for continued coverage for this treatment.

Sincerely,

Dr. Christine Foss.

8-1-06

To Whom It May Concern:

My name is Paul Fecteau PT/SCS/ATC and I work at Bader Physical Therapy in Norway, ME. I have been using Anodyne with diabetic and non-diabetic neuropathy patients for the last 4 months. The limitations of these patients range from numbness and burning to their feet to loss of balance and altered gait.

Over the past 10 years as a Physical Therapist I could only exercise these patients and their improvement was limited – I would usually recommend a neurologist after the completion of a failed 4-8 week course of physical therapy. I was skeptical initially when my employer purchased an Anodyne unit but I'm glad to say I have seen amazing results combining Anodyne with balance training, gait training, home program instruction and progressive resistant exercise.

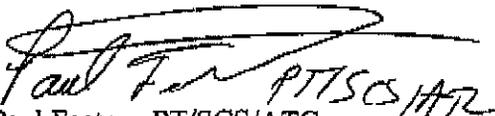
I am now helping patients I previously was unable to help. They are reporting less numbness/burning, improved ability to do activities of daily living, less dependence on assistive devices, and a better tolerance to an exercise program. Objectively we are seeing noted improvements with the Tinetti balance and Tinetti gait scores.

We are currently discussing a way to measure patients subjective and objective improvements using Anodyne, and put the information into a database, but that is not in place yet.

I hope that Medicare will continue to cover Anodyne Therapy, not only in the clinic but also the home unit. As you may be aware, for patients to see continued progress they need to get a home unit at their completion of physical therapy in the clinic. I firmly believe that Medicare covering Anodyne Therapy in the long run will decrease the amount of medical care needed for diabetic neuropathy patients due to increased dependence on others for independence, decreased circulation (possible increased risk of foot ulcers/open wounds), decrease balance (possible increased risk of falls), and decreased endurance (increased systemic problems due to a less active lifestyle).

If you should have any specific questions I would be happy to speak with you.

Sincerely,


Paul Fecteau PT/SCS/ATC



4500 Memorial Drive
Belleville, Illinois 62226-5399
(618) 233-7750
FAX: (618) 257-5658

Harry R. Maier, *President*

August 9, 2006

Louis Jacques, MD
Division of Items and Devices
Coverage and Analysis Group
Office of Clinical Standards and Quality
Dept. of Health & Human Services
Centers for Medicare and Medicaid Services
7500 Security Blvd, Mailstop C 1-09-06
Baltimore, MD 21244-1850

RE: Proposed Decision Memo for Infrared Therapy Devices

Dear Dr. Jacques,

I am a Physical Therapy, Director of a Rehabilitation Service in Southern Illinois. I have 46 years experience in Physical Therapy. The Hospital Rehabilitation Service I direct sees over 10,000 outpatients a year, many of them on Medicare and Medicaid. Among these people, are many who have peripheral neuropathy, diabetic and non-diabetic; who have had no relief with medical care. Their loss of sensation and discomfort has continued in spite of medication, ointments, over the counter aides, physical therapy of various types, exercise and balance training. They remained susceptible to falls, fractures, fear, sleeplessness, disorientation, daily discomfort and a narrowing social contact due to all of the above.

I believe, in spite of all your negative findings, that a large enough population of Medicare recipients react positively to MIRE care, that it is worth offering, and would be a disservice to not offer MIRE to Medicare insured patients.

Remember: there is no other effective modality or medication. This is a very hard to care for problem that with its chronic nature leads to severe disability and premature death. Comparing costs to Medicare in human suffering and money for MIRE versus a fractured hip may be worthwhile before making a negative determination. This problem effects a large senior population.

Have you wondered why we continue to offer MIRE when we are reimbursed \$5.07 per visit by our local Medicare carrier? We are not making a living on this service. However, we are here to serve our patients. We see this work on an acceptable number of these, often desperate, seniors who have tried other treatment without success, get better, in one way or another. They are very grateful, and speak well of us in the community. We will continue to offer MIRE, whether you pay or not. We have found it to be that valuable to our patients and our community.



4500 Memorial Drive
Belleville, Illinois 62226-5399
(618) 233-7750
FAX: (618) 257-5658

Harry R. Maier, *President*

I would hope the affirmative information you receive will be weighed appropriately. If we look at all the things we do for patients, including medicine, surgeries, injections, PT/OT/Speech procedures, that do not have hard objective experimental evidence of efficiency, I am sure we would find procedures of more expense and dubious value than MIRE.

Light therapies are amazingly effective for myofascial and joint pain and dysfunction. They allow us to do the manual therapies, exercise, and functional training sooner and more intensively; thereby getting patients on the road to recovery sooner. With insurance limitation this is very necessary. I am fearful you may "paint with a large brush" as we often see government do, and throw out an extremely valuable tool. Light therapy will only get better with the work being done in patient care and research. I see my therapists using light more and more. Why? Because we make so much money for it? I am afraid not -- they use it because it is effective.

I am attaching for your information, an inquiry we did of our MIRE, peripheral neuropathy treated patients the first year we made it available. Please, as you look at this remember the difficulty in care of peripheral neuropathy, and the fact, there is no present medical, surgical, OTC, chiropractic, or alternative medicine care, that works for these patients.

Sincerely,

MEMORIAL REHABILITATION SERVICES

Donald C. Courtial, PT
Director of Rehabilitation Services

cc: Dr. Jeffrey R. Basford, MD, PhD
Mayo Clinic – Physical Medicine and Rehabilitation

ANODYNE QUESTIONNAIRE FEEDBACK

(start of anodyne treatment to March 2006)

Results were based on 31 questionnaires returned.

1. Did anodyne help your peripheral neuropathy?

Yes: Short term (up to 2 months) 16

Long term (over 6 months) 10

No 2

Blank 5

2. Did you receive a home unit?

Yes 8

No 22

3. Symptoms that were helped with treatment

Pain/ache 15

Loss of sensation 11

Swelling 1

Electric shocks 2

Walking 13

Medication decrease 3

Numbness 17

Tingling 11

Burning 9

Balance 11

Sleep problems 7

Remarks:

"I didn't know there were home units."

"If it were not for the long distance I would ask my doctor for more treatments."

"At first it appeared to help a little, but then I wasn't noticing any change."

"All of the above was helped from the time I got the treatment until now."

"I have the tingling in my hand and wrist."

"Could you check with my insurance to see if they would pay for a home unit or pay for part of it. If not could you tell me what kind of a payment plan you offer."

"Good organization. Very short waiting time. Very helpful suggestions."

"I have pins and needles symptoms that went into total numbness. Now- I'm getting feeling back."

"The unit also helps with the circulation in my legs."

"I do this at least three times a week. I know my sleep is better. I still have feelings of electrical shock but nothing like before."

"The first twelve treatments I could see much improvement in balance and numbness."

"Felt good."

"Helped mentally – keep trying to find help for neuropathy patients."

"I think a long term anodyne would be beneficial."

"Went from almost constant pain when walking to 3 1/2 mile walks virtually pain-free."

"I had only half of the program but I still saw results."

"Unfortunately my HMO permitted me only 10 sessions. I felt my balance was improved, I have a dropped foot. I believe a full program of 20 treatments would have been productive. I realize anodyne is like most procedures and pills varies in success. My experience was effective I'd like to continue the treatments."

"Started anodyne about Sept 2005. As of about May 2006- if anodyne used every other day for 45 minutes each leg pain now peaks to a 3, if only 2 times weekly pain peaks to 7 or 8. Don't know why pain has returned. My circulation still seems a lot better so I don't know what is happening. I believe something has been wrong with my unit since day 1. I tried to explain to anodyne and the said cut my 45min to 15min. if I did that it would be useless. It only does 1 leg at a time and it starts to burn me bad on the first leg. Also another difference between beginning and now is new house has stairs. So I've been walking stairs for 3 month now. Maybe this is why anodyne is not as effective as it use to be? Don't know for sure. Also had to stop physical therapy due to degenerative disc disease. Miss your cheerful attitude Don!"

4. Would you recommend this treatment to a friend?

Yes 23

No 3

Blank 1

Maybe 1

Depends 1

5. How could we have served you better? What would you suggest to make our service better?

Positive responses

"I would like to try some more treatments. I will discuss this with my doctor."

"The rehab service is fine. The treatment just didn't work for me."

"People were helpful and nice. I just wish it would have helped me."

"Service and treatment were excellent! Please let me know if medicare approves a second service."

"The care was excellent! The assigned P.T. gave great care. Her attitude and professionalism was greatly appreciated - Thank you."

"Staff is great from receptionist (appointment maker) to your P.T.'s and assistants. Tim at other outpatient office referred me to you, but it would be nice to go to your outpatient office for treatment as well. I have told every medical person I know what good results I've had and to come to Memorial for their rehab!!!"

"I could not suggest anything to make your service better, because I was well pleased with your service. Everyone who helped me was really great."

"I was very pleased when I come to Memorial for this treatment. I couldn't have been treated any better."

"The staff was very friendly and answered any questions that I had about the therapy."

"Service was good."

"Your service and staff were tops. I just think the treatment wasn't right for me. Thank you for your support."

"Service is good, personnel very friendly."

"Perhaps it would help someone with diabetes (I don't have) or just another person. I did enjoy the treatments and Don Courtial and his staff for their courtesy and their efforts to help me"

"Staff at Memorial was excellent!"

"The treatment may help the next patient. Your service was very good and very prompt."

"The treatments really helped. And thank you Don for your extra efforts in getting me a machine at home. I use it every other day. (I can tell if I miss a few days)."

"Very satisfied- very prompt service- on time with little wait. Very helpful when working with doctor to achieve maximum results. Thank you. Great job Don and team!"

"Did a good job."

"I was satisfied with your management. I believe you're on the right path."

Negative responses

"The length of the treatment varied by therapist. I benefited more from the light than massage."

"The cost of a home unit and what the payments would be. If this is possible. But first see if insurance will pay anything."

"Offering of home units as rental or at a reduced amount through the supplier."

"Provide some overview by a medical doctor when legs are wrapped for lymphedema."

"A few of your P.T.'s don't follow through on all the exercises."

"Don't know except sending this form sooner so it is easier to remember."

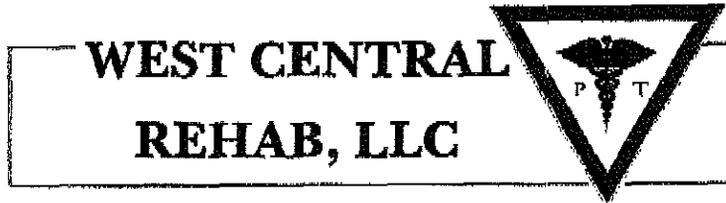
"Home unit doesn't work as well as hospital unit and burns bad when ran 45 min x 2. Hospital service were excellent- just home unit sucks."

"No help at all."

"It felt good during treatments. But feet still burned later. I bought and returned home unit. It was no help"

"Did not help the type of neuropathy I have."

"Treatment did not have beneficial effect for me."



08/10/06

p-1

Attention: Medicare NCD Comments
Anodyne Therapy, LLC
13570 Wright Circle, Tampa, FL 33626

Medicare NCD Comments,

I am a Physical Therapist with an independent Practice in Baldwin Michigan since 1981.

I have treated many patients during this time but none have been treated for neuropathy pain because no procedure was available.

I purchased 2 units (infrared) in October of 2005. Since that time I have treated (18) patients with diabetic neuropathy and 1 patient with a neuropathy from unknown cause.

Every patient that I have treated has responded to the infrared treatments to both lower extremities.

This procedure has done the following.

- 1) Decrease irreversible foot pain from 10/10 to 0/10.
- 2) Improve foot-sensaton- in the feet from 0/10 positive areas of sensation to 10/10 positive locations.

The benefits of this improved sensation.

- 1) Improves balance and in the long run will prevent falls.
- 2) This also improves patient's quality of life.
- 3) Wound healing. Two patient's small wounds have healed in 3-5 days. One patient with a large wound (soft ball size) open for 3 years has started to grow new skin and is 2.0 centimeters smaller in size.

As you know the treatment is not a permanent treatment for the symptoms returning in 1-4 weeks following the last treatment. I have had patient's purchase (5-6) units for home use.

Continue, Medicare Comments next page....

Continue, Medicare Comments...

p-2

In conclusion - Medicare would be foolish if they don't cover this procedure - and pay for home units. The following cost would be eliminated.

- 1) The cost of pain medication.
- 2) Treatments to diabetic wounds and expenses for amputations.
- 3) Prevents falls resulting in fractures.

Please consider very carefully the over all picture of costs before you exclude Infrared treatments for the large number of people who develop diabetic symptoms in their Medicare years.

Sincerely,

David L. Bales PT

David L. Bales, PT
DLB.sg

NEUROLOGY ASSOCIATES OF FORT WORTH

Roger S. Blair, M.D.

Diplomate of the American Board of Psychiatry and Neurology (In Neurology)
Diplomate of the American Board of Electrodiagnostic Medicine
Diplomate of the American Board of Psychiatry and Neurology (In Clinical Neurophysiology)
Fellow of the American Academy of Disability Evaluating Physicians
Fellow of the American Association of Electrodiagnostic Medicine

Electromyography
Evoked Potentials
Videonystagmography
Electroencephalography
Independent Medical Examination

Larry Hayward, PA-C

Licensed by the State Board of PA Examiners
Certified by the NCCPA
Masters of Exercise Science

August 11, 2006

To Whom It May Concern:

I would like to respond to the Medicare proposed decision memo for infrared therapy devices. I disagree with the decision to issue a non-coverage draft policy for infrared therapy. I have prescribed infrared therapy (Anodyne) to over 100 patients for diabetic peripheral neuropathy and idiopathic peripheral neuropathy. Many of my patients have reported improvements in feeling, pain, discomfort, and balance. I have a large number of patient's who were so pleased with the improvements they acquired home units for continued use. I feel it would be detrimental to the quality of life of many of my patients, if they were no longer able to afford the therapy. Thank you for your time.

Sincerely,



ROGER S. BLAIR, M.D.

RSB: lh

cc: Attention: Medicare NCD Comments
Anodyne Therapy, LLC
13570 Wright Circle
Tampa, FL 33626
Fax: 866-314-1642

CRNC, INC. DBA

PHYSICAL THERAPY SOLUTIONS

2838 Andrews-St.
Pascagoula, MS 39567

Phone: (228) 762-2345
Fax: (228) 762-2365

August 14, 2006

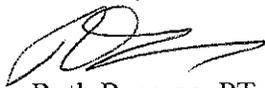
To Whom It May Concern:

I am a physical therapist in Pascagoula, MS with twenty-four years of experience treating patients with neuropathy symptoms and neuropathic pain. The pulsed infrared light treatment is the first physical therapy treatment that I have encountered that provides these patients any lasting relief of their symptoms and allows them to progress through rehabilitation more rapidly.

Many of our patients struggle with burning pain in their feet at night when they are trying to sleep. They are pleasantly surprised when the pulsed infrared light treatment controls these symptoms and they are able to sleep without the use of strong medication.

Please consider the continuation of coverage of this service by Medicare.

Sincerely,



Ruth Bosarge, PT, CMDT

CARROLL COUNTY MEMORIAL HOSPITAL
Rehab Department
1502 North Jefferson
Carrollton, MO 64633
660-542-1664

8/08/06

MEDICARE NCD Comments

Dear Sirs:

I am writing concerning the proposed non-coverage policy for Anodyne Therapy and Anodyne Home Systems. As a licensed physical therapy assistant, I have found that Anodyne Therapy has been extremely successful in treating diabetic neuropathy by producing improved sensation and decreased pain allowing better range of motion and gait. These patients that have received Anodyne Therapy have become safer ambulators, more active people and overall achieve a better level of health than prior to the Anodyne treatment.

We have been extremely pleased with the outcome of the Anodyne product and we have case studies that we can produce concerning the outcome and the reduction of pain. Most out patients would not be inclined to involve themselves with a home unit if they did not feel that they needed it.

Please reconsider the proposal for non-coverage for infrared therapy because it has been instrumental in pain control and improvement in patient function.

Sincerely,

Jeanie Brown, PTA



2100 Stewart Avenue
Suite 240
Wausau, WI 54401

tel 715.845.9283
fax 715.848.2493
email information@aslms.org
web www.aslms.org

August 7, 2006

Steve Phurrough, M.D., MPA
Director, Coverage and Analysis Group
CMS, HHS

RE: **Proposed Decision Memo for Infrared Therapy Devices (CAG-00291N)**

Dear Dr Phurrough:

I am writing in response to the above captioned proposed decision memo, in my capacity as the current President of the American Society for Laser Medicine and Surgery (ASLMS) and on the behalf of its Board of Directors and members. The purpose of my correspondence is to express our concern that the proposed decision will prove detrimental to patients, patient care and research, if adopted.

ASLMS is a multispecialty, multidisciplinary organization with a membership of approximately 4000. It is the largest organization of its kind and is dedicated to the enhancement of understanding and application of lasers and related technologies in biomedicine. It is an open Society that includes both academic and practicing physicians, as well as allied health professionals, scientists and representatives of government and industry. ASLMS promotes dialogue between these varied constituencies. Our members include scientists, researchers and clinicians from across North America in addition to other global members. A number are affiliated with NASA, DARPA, FDA and several sit on CMS, NIH and FDA advisory panels. *Lasers in Surgery and Medicine*, the Society's Journal is considered to be the leading resource for information on topics in this growing discipline.

Photobiomodulation has been an integral part of our Society's Annual Meetings and its publications and proceedings from the inception of our organization. Clinical and laboratory investigations relative to the mechanisms, optimal parameters and utility of light-based therapies are presented, discussed and are published in our literature. "Infrared Therapy" as it is described in the proposed decision (NCD) is a subset of light-based treatments using lasers, light emitting diodes, SLDs and other devices emitting energy in the near infrared spectrum. Applications of these devices are often bundled into terms such as "low level laser therapy" (LLLT), "phototherapy", "photoradiation", "low intensity light therapy" and other terms.

This expanding array of devices is often applied in conjunction with devices emitting in the red spectrum. FDA clearance has been granted to a growing list of manufacturers, for use of these technologies "in the adjunctive treatment of musculoskeletal disorders." There is a large body of research indicating that infrared and other wavelengths of light offer a safe and effective method of treating numerous clinical conditions, including wounds, musculoskeletal disorders, carpal tunnel syndrome and other disorders.

The bibliography posted along with the proposed decision includes 244 references. However, there are many notable omissions from the bibliography. A single reference to Abergel is included, which discusses

executive committee

Thomas M. Brunner
Los Altos Hills, CA

A. Jay Burns, M.D.
Dallas, TX

Christine C. Dierickx, M.D.
Boom, Belgium

Ellet H. Drake, M.D.
Sanibel, FL

Roy G. Geronemus, M.D.
New York, NY

Richard O. Gregory, M.D.
Celebration, FL

J. Stuart Nelson, M.D., Ph.D.
Irvine, CA

E. Victor Ross, M.D.
San Diego, CA

laser tissue fusion rather than other work from his group on angiogenesis, collagen production, fibroblast activity and other effects of LLLT. The works from Anders and her group on nerves and spinal cord regeneration, and Rochkind's nerve regeneration studies using various wavelengths is absent. The work of Whelan and others on wound healing, musculoskeletal and other disorders, using NASA LED devices emitting in the near infrared and red spectra are not cited.

The ability to influence collagen production and collagen metabolism is of great interest to dermatology as well as to all who are involved with wound healing or tissue integrity. The work of the McDaniels group relative to the effect of specific wavelengths of light on the mitochondria, collagen, collagen metabolism and the skin is well-known to our membership. This body of research has not only led to the FDA approval of devices for dermal tightening, but has also provided a good deal of insight as to the mechanisms of photobiomodulation and the utility of these treatments when applied appropriately. Many other notable investigators appear not to have been included in the supplied list of references.

Thousands of scholarly papers including randomized controlled studies and a number of meta-analyses have been written about the clinical outcomes achieved with these wavelengths of energy. Many authors have demonstrated that the appropriate application of these technologies can accelerate wound healing in both normal and impaired hosts, when phototherapy using appropriate wavelengths and treatment parameters are administered adjunctively. We do not mean to imply that these therapies represent a panacea for these refractory conditions. However, even considering "conventional" approaches for these complex conditions, one realizes that there are many alternatives, none of which achieve 100% results. One such example is the treatment of carpal tunnel syndrome for which LLLT is an FDA approved indication using these devices. A 20% response rate is obtained, which is consistent with other nonsurgical therapies for this condition.

While the Agency might consider that the application of these techniques is controversial and with both pro and con literature, there is a growing body of evidence supporting positive photobiological events in the target patient population. While it is arguably correct to state that use of light therapy is not "necessary", a growing body of evidence demonstrates that it is indeed "reasonable". Irrespective of the Agency's ultimate decision concerning reimbursement for these technologies, we urge that they should consider modifying the statements relative to "reasonable" and "necessary".

Based on the foregoing information and the specific mention of the Anodyne device throughout the NCD memo, it appears that the proposed decision is directed toward a very specific product rather than the general category of technology bundled under "Infrared Therapy Devices". This decision will unfairly impact the entire category and other devices. The ramifications of such an approach could have far reaching consequences for clinicians, who use a variety of modalities, as well as being extended to infer that all forms of phototherapy are without merit.

The NCD references an FDA communication to a specific manufacturer, calling attention to multiple reports of burns resulting from the use of monochromatic infrared energy (MIRE). It appears that the Agency has limited and inaccurate information and is castigating an entire discipline on the basis of a problem with a single device from a single manufacturer. Safety issues and off label use problems specifically occurring with the use of the Anodyne product (or others) may be directly related to a specific instrument design or a specific manufacturer's product. These should be appropriately addressed by the FDA and the manufacturer, and should not be applied to all devices.

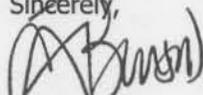
While the Agency has reached out to numerous organizations involved with wound and patient care, none of the organizations listed have specific expertise relative to photonics or photobiomedicine. The

Steve Phurrough, M.D., MPA
Page 3
August 7, 2006

American Society for Laser Medicine and Surgery may provide additional information and more specific expertise on these topics. ASLMS can offer itself or its members as experts, advisors and can provide resources to the Agency on this and/or other photobiomedicine related issues placed before it for adjudication.

It is our hope to assist the panel or provide consultation to the review process to ensure that this vast wealth of research and clinical experience is incorporated into the decision making for the use of infrared energy or other light based therapies relative to patient care.

Sincerely,

A handwritten signature in black ink, appearing to read "A. Jay Burns". The signature is stylized and somewhat cursive.

A. Jay Burns, M.D.
President, ASLMS

S.B.J.S. PC
DBA SOUTHERN
BONE & JOINT
SPECIALISTS



THE PRACTICE OF
 ORTHOPAEDICS

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 R. DEAN LOLLEY, M.D.
 DAVID W. ALFORD, M.D.
 O.H. (SKIP) CHITWOOD III, M.D.
 FLEMING G. BROOKS, M.D.
 PATRICK W. LETT, M.D.
 TIMOTHY M. HALEY, M.D.
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 WILLIAM B. HANSON, M.D.
 JOHN H. HALEY, JR., M.D.

BONNIE J. DUNGAN, M.D.
 PHYSICAL MEDICINE AND REHABILITATION
 MARK E. CHOQUETTE, SR., M.D., F.A.C.P.
 BENJAMIN J. WERNER, D.P.M.
 PODIATRIC SURGERY & MEDICINE

MITON H. WOOD, C.E.O./ADMN.

EAST LOCATION:
 1500 ROSS CLARK CIRCLE

WEST LOCATION:
 FLOWERS HOSPITAL
 4300 WEST MAIN STREET, SUITE 14

ENTERPRISE LOCATION:
 404 NORTH MAIN STREET
 (334) 308-9797

August 14, 2006

Medicare
 NCD Comments Anodyne Therapy, LLC
 13570 Wright Circle
 Tampa, FL 33626

Re: Anodyne Therapy

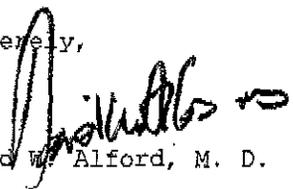
To Whom It May Concern:

I am an orthopedic surgeon specializing in foot and ankle disorders. It is my opinion that Anodyne therapy is the one benefit that patients with diabetic and nondiabetic neuropathy have that has been extremely effective in my practice. Patients who have this difficulty are often frustrated, miserable and medications are of limited benefit. I have many patients who have been treated with Anodyne therapy and have gotten marked improvement, significant relief, and complete resolution of their burning pain that is from diabetic neuropathy.

Please do not discontinue coverage of Anodyne therapy by Medicare. I think you would be doing a great disservice to your patients who need this treatment.

If I can be of any further assistance in answering these questions, please do not hesitate to call.

Sincerely,


 David W. Alford, M. D.

DWA/ca

To avoid delay, transcribed but not read.



ST. AUGUSTINE HEALTH CAMPUS

Continuing the Healing Ministry of Christ

JULY28, 2006

To whom it may concern:

I am a physical therapist with 20 years of experience in acute and long term rehabilitation facilities, as well as in outpatient clinics. I have vast experience with the whole range of therapeutic modalities including Anodyne infrared therapy. While many of the modalities prove helpful as adjuncts to musculoskeletal disorders, many of their benefits are "per patient report". I began using Anodyne therapy as treatment for diabetic neuropathy approximately 5 years ago. I was quite skeptical at first because this is a very difficult population to treat. They often arrive in the clinic having tried a variety of pain medications and ointments with little or no improvement. Their balance is poor, and their skin is often not intact with long-standing ulcers. I was stunned to see not only an improvement in painful symptoms but an actual improvement in sensation and balance as objectively measured by the Seimmes-Weinstein sensation test and Tinetti Blance scale. While my clinical treatment plan was aimed at improving balance and sensation and decreasing painful symptoms, I began to see improvement in the foot ulcers that were being indirectly treated by the Anodyne. Since February of this year, I have treated a number of full thickness wounds 5x/week with very positive results. One gentleman with peripheral neuropathy had a dehissed BK amputation site measuring 9.7 cm x 7.0 cm x 4.0 cm. After 4 months his wound measured .4 cm x .3 cm. As a clinician I am very distressed that CMS would consider depriving their patients of a modality that clearly benefits their patient. Good treatment of wounds, balance deficits, and chronic pain will save CMS millions of dollars in the long run.

Thank-you for your consideration in this very important matter.

Sincerely,

Suzanne Arroyo, PT

Rehabilitation, Subacute, Skilled Nursing
at St. Augustine Manor
7801 Detroit Avenue
Cleveland, Ohio 44102
216-634-7400 fax: 216-634-7483



Assisted Living
at St. Augustine Towers
7821 Lake Road
Cleveland, Ohio 44102
216-634-7444 fax: 216-634-2717



Child Enrichment Center
at St. Augustine Manor
7801 Detroit Avenue
Cleveland, Ohio 44102
216-939-7600 fax: 216-634-7483



HEALTH CARE OPTIONS, INC.

CELEBRATING 20 YEARS

August 8, 2006

VIA FACSIMILE TO (866)314-1642

Attention: Medicare NCD Comments
Anodyne Therapy, LLC
13570 Wright Circle
Tampa, Florida 33626

Re: Medicare NCD Comments

Dear Sir/Madam:

What can be said? What is the cost of a limb or a foot versus receiving an infrared therapy treatment protocol?

This therapy saves limbs and feet. Why not pay a fraction of the cost for care to save millions on the cost of losing a limb and the after-care involved in such a loss.

Let's not do a disservice to our community. **Cover** anodyne infrared therapy.

Thank you for your attention to this letter. It is greatly appreciated.

Sincerely,

A handwritten signature in black ink, appearing to read "Annette Austin", written over a horizontal line.

Annette Austin
Chief Executive Officer

MDM/btr



HEALTH CARE OPTIONS, INC.

CELEBRATING 20 YEARS

August 8, 2006

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Thank you for your attention to this letter. It is greatly appreciated.

Sincerely,

A handwritten signature in cursive script that reads "Rosalene Alexander".

Rosalene Alexander
Director of Nursing/Administrator
Health Care Options, Inc. - Lafayette

MDM/btr

August 13, 2006

To Whom It May Concern:

I read, with alarm, that Medicare is in the process of issuing a Non-Coverage Draft Policy for Anodyne Therapy. As a Clinician and a Director of a Rehabilitation Department that services primarily the geriatric population, I strongly object. Our department has used Anodyne Therapy, along with other Physical and Occupational treatments, and has found it highly effective in reducing pain, improving sensation, improving balance and improving function. Most of all, it has improved the quality of life for most of our patients who had nearly given up hope for improvement. Our clinic uses objective measures that are standardized and approved by the APTA and OTA. In our tests and measures we have included the nationally recognized Berg Balance Scale, Philadelphia Pain Scale and the Semmes-Weinstein Monofilament Tests. These tests are objective measures of balance, pain and sensation. Our clinic has treated over 80 patients in the past two years and I am proud to say that 90% of our patients demonstrated measurable improvement. The patients who did not benefit were either non-compliant with the treatment regime or had multiple medical issues that complicated the outcomes.

As you know there are multiple medications on the market for the reduction of pain. However, with the geriatric population, taking another pill may place them at greater risk for falls, and may be more costly for Medicare in the long run. I find it ironic that Medicare thinks it will be saving money if it stops paying the \$5.00 that it gives the Clinician for the half hour Anodyne treatment, but would pay \$30.00 for a pain pill that has to be taken every four to 6 hours 24 hours a day seven days a week. In addition, the home unit, which costs Medicare approximately \$2500.00, is a one-time expense. I have patients who have had their units for over two years without any mechanical defects.

I would like to end my appeal to Medicare by telling the story of a 77 year- old woman who came to my clinic with a referral for Anodyne Therapy. She had Diabetic Peripheral Neuropathy. She had seen her neurologist over many months because she was no longer able to hold her fork, button her clothes, and her hands kept slipping the steering wheel of her car when she drove. Her Neurologist tried all he could do medically to no avail. He referred her to us as a last ditch effort. After twelve therapy treatments using the Anodyne Therapy along with other therapy interventions, she improved in sensation, strength and fine motor coordination. She could hold a fork, button her clothes, knit and drive safely. She got her life back again! Her family was so excited that they all chipped in and got her the home unit! Please, do not take this valuable tool away from our patients who need it!

Sincerely,

Evelyn McKay, PT, Director of Rehab Services, Southington Care Center



August 8, 2006

VIA FACSIMILE TO (866)314-1642

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Anodyne Therapy, LLC
13570 Wright Circle
Tampa, Florida 33626

Re: Medicare NCD Comments

Dear Sir/Madam:

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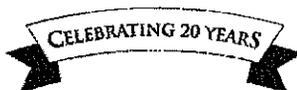
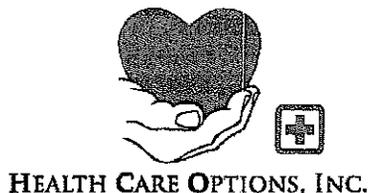
Let's not do a disservice to our community. **Cover** anodyne infrared therapy.

Thank you for your attention to this letter. It is greatly appreciated.

Sincerely,

Maxine D. McCrary
 Maxine D. McCrary
 Vice President of Operations
 and Director of Nursing

MDM/btr



August 8, 2006

VIA FACSIMILE TO (866)314-1642

Attention: Medicare NCD Comments
Anodyne Therapy, LLC
13570 Wright Circle
Tampa, Florida 33626

Re: Medicare NCD Comments

Dear Sir/Madam:

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Let's not do a disservice to our community. **Cover** anodyne infrared therapy.

Thank you for your attention to this letter. It is greatly appreciated.

Sincerely,

Maria McCraney
Director of Staff Development

MDM/btr

CARROLL COUNTY MEMORIAL HOSPITAL
Rehab Department
1502 North Jefferson
Carrollton, MO 64633
660-542-1664

8/08/06

MEDICARE NCD Comments

Dear Sirs:

I am writing concerning the proposed non-coverage policy for Anodyne Therapy and Anodyne Home Systems. As a licensed physical therapist, I have found that Anodyne Therapy has been extremely successful in treating diabetic neuropathy by producing improved sensation and decreased pain allowing better range of motion and gait. These patients that have received Anodyne Therapy have become safer ambulators, more active people and overall achieve a better level of health than prior to the Anodyne treatment.

We have been extremely pleased with the outcome of the Anodyne product and we have case studies that we can produce concerning the outcome and the reduction of pain. Most out patients would not be inclined to involve themselves with a home unit if they did not feel that they needed it.

Please reconsider the proposal for non-coverage for infrared therapy because it has been instrumental in pain control and improvement in patient function.

Sincerely,

Nancy Spock PT

Stotts



Alpha Omega Home Health Services, Inc.
10461 Commerce Row
Montgomery, TX 77356
936/447-2900 metro
936/447-2999 fax
800/269-8542 toll-free

August 8, 2006

Medicare NCD Comments
Anodyne Therapy, LLC
13570 Wright Circle
Tampa, FL 33626
866/314-1642 Fax

I have read of Medicare's proposal to cease coverage for patient treatment with infrared devices. This decision is short-sighted and ill-informed. I urge that it be reversed.

Our Agency has treated dozens of patients using infrared therapy. To a patient, they have all responded positively to the therapy. In varying cases the therapy has relieved pain, improved blood circulation, and healed chronic wounds. These outcomes can dramatically improve and increase patients' daily activities of living and quality of life.

We have had chronic, long-term wound care patients improve to the point where they no longer needed Medicare-covered home health services. Chronic neuropathy patients have said after undergoing infrared treatment they have had their first pain-free movement in a decade, or longer.

Limiting or removing Medicare coverage of infrared therapy will take a very powerful clinical tool out of the hands of physicians and therapists.

I urge you to reconsider this decision, and to continue Medicare coverage of this form of therapy.


Janet M. Stotts, RNC
Director of Nursing

Advanced Physical Therapy Center, INC.

999 Summer Street, Stamford, CT 06905-5513
 203.359.8326 • Fax 203.352.1912
 www.AdvancedPTC.com

Jill Tomasello, PT, OCS, FABDA, Cert. MDT
 Board Certified Specialist in Orthopedics
 Fellow, American Board of Disability Analysts
 Certified in Mechanical Diagnosis & Treatment
 (The McKenzie Method)

Janet Hartney, MS, PT
 Integrated Manual Therapist
 Pain Specialist

Gigi Kearney, PT, Cert. MDT
 Certified in Mechanical Diagnosis & Treatment
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 Women's Health

Samara DiMatteo, MS, PT
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Maureen Meehan, PT, Cert. NDT
 Certified in Neuro-Developmental Technique
 Rehabilitation Medicine

Stephanie Raefski, MSPT, OCS, CLT
 Board Certified Specialist in Orthopedics
 Certified Lymphedema Therapist
 Blocked Duct Therapy

Neil Chernick, MSPT, OCS, CSCS
 Board Certified Specialist in Orthopedics
 Certified Strength & Conditioning Specialist
 Sports Medicine

Christina Machielson, MSPT, OCS
 Board Certified Specialist in Orthopedics
 Integrated Manual Therapist
 Orthotic Consultant

Marrit Rosenlof, ATC
 Certified Athletic Trainer
 Aquatic Instructor

Kenan Trebinjevic, MSPT
 Orthopedics
 Sports Medicine

Brian Kelley, MSPT
 Orthopedics
 Sports Medicine

David Ponucek, MSPT
 Orthopedics
 Sports Medicine

Dave Nebiolo, DPT, MS
 Orthopedics
 Golf Instructor

Cindy Potter
 Office Manager

To Whom It May Concern:

We have just been informed that Medicare has issued a non-coverage draft policy for infrared therapy devices, because it is not reasonable and necessary for treatment for diabetic and non-diabetic peripheral neuropathy. Our clinic has recently started using the infrared modality and we have conducted a study on our patients to determine the effectiveness of the device. Our research has shown that our patients have made drastic improvements in balance, gait and sensation testing since the beginning of treatment.

For the 4-week study period, we had six subjects participate in the study, 3 with diabetic peripheral neuropathy and 3 with non-diabetic peripheral neuropathy. We assessed patients balance with 2 different scales, the Berg Balance Scale and the Tinetti Assessment Tool. The Berg Balance Test assesses patients balance on a 56 point scale. Anything less than a 41 indicates the patient should be walking with assistance and is at risk for falls. Of our 6 subjects, 4 subjects started in the walking with assistance group (39/56, 34/56 and 35/56 respectively) and increased to the independent/no fall risk group (50/56, 51/56, 46/56). Two subjects started in the low end of the independent group with scores of 42/56 and 45/56, but both increased their scores to 52/56. All subjects increased on the Berg Balance Test by 13 – 30% after the 4-week study period.

The Tinetti Assessment Tool assesses both balance and gait. The maximum total score possible is 28 points. A score below 19 points indicates a high risk of falls and a score between 19-24 points indicates a minimal risk of falls. Of our 6 subjects, 5 subjects started in the high fall risk category, 1 in the minimal fall risk category. After treatment with infrared light therapy, all subjects improved to the minimal fall risk category and 2 subjects ended in the no fall risk category. All patients increased on the Tinetti Assessment Tool 21 – 43% after the 4-week study period.

Additionally we assessed pain with an 11-pt visual analog scale. Three patients had a 30 – 40% decrease in pain after the testing period and two patients had no complaint of pain. Finally we assessed sensation via the monofilament testing. Subjects demonstrated an increase in sensation of 20 – 80% when comparing initial evaluation to discharge evaluation.

As you can see, the infrared light therapy modality has dramatically improved our patients' quality of life and lowered their risk of injury. They have demonstrated increased balance, increased gait and increased sensation after a trial of the modality. Subjectively, they have complained of less pain, increased balance and increased ability to perform home and work ADL's. Therefore, we ask that you reconsider the non-coverage draft policy for infrared therapy devices.

Petrone

Jennifer Turtzo

From: Joseph Petrone [jpetrone@mtsu.edu]
Sent: Monday, July 31, 2006 3:59 PM
To: medicare@anodynetherapy.com
Subject: Anodyne Success

To Whom It May Concern:

I have used Anodyne since it was developed to heal patients and to decrease pain. It has a place in the Health Care field. I am a Certified Athletic Trainer that has access to many modalities to work with! I have never been closed minded about trying to help someone get better or improve medically. So when Anodyne was introduced to me for Diabetics to help decrease pain and increase blood flow to wounds I had to give it a try. I had a chance to use it on several different open wounds that would not heal with conventional methods, so I figured to try Anodyne on these wounds! It did work and I might add it work in a short period of time; that the patient was wondering why other clinics did not use them for pain reduction and to increase blood flow to the area that would not heal. I could go on and on about the success I have had with Anodyne at the clinic I worked at, but I am at a college setting now and I had a chance to use it on my best friends son who hurt his foot and ankle in a go-cart crash. He open up a wound on his ankle that he had a plastic surgeon had to treat. The surgeon wanted to do skin grafts to his ankle area, but the kid wanted to finish out football season before he had the surgery. My friend told him that I could pad the wound to keep trauma to the area down to a minimum told them we could use the Anodyne to increase blood flow to the wound that might make it feel better and could speed up the healing process. The Doctor was "OK" with this and wanted to see him back in 2 weeks. We treated for 2 weeks 5 days a week for 20 minutes to the wound site. When he went back to the Doctor for a 2 week check up, the doctor was very please with wound healing process so much that he wanted to try 3 more weeks and may be he wanted not need a skin graft. Long story short the kid had a complete recovery and did not miss any football thanks to Anodyne and the Plastic Surgeon that did not have a ego or a close mind about infrared light therapy. To close if we do not try to make advances in Health Care, WHY CARE AT ALL!!!!!!
Thank You for Your time, Joe-Joe Petrone ATC/L





August 8, 2006

VIA FACSIMILE TO (866)314-1642

Attention: Medicare NCD Comments
Anodyne Therapy, LLC
13570 Wright Circle
Tampa, Florida 33626

Re: Medicare NCD Comments

Dear Sir/Madam:

What can be said? What is the cost of a limb or a foot versus receiving an infrared therapy treatment protocol?

This therapy saves limbs and feet. Why not pay a fraction of the cost for care to save millions on the cost of losing a limb and the after-care involved in such a loss.

Let's not do a disservice to our community. Cover anodyne infrared therapy.

Thank you for your attention to this letter. It is greatly appreciated.

Sincerely,

Lisa Jasper
Branch Director
Health Care Options, Inc. - Gonzales

MDM/btr

EPC Outpatient Services

A Service of NORTHWEST HEALTHCARE

FR. Haidle, PT
Mark Anthony Fink, PT
Lisa Spors-Murphy, MOT, OTR

August 8, 2006

Attention: Medicare NCD Comments
Anodyne Therapy, LLC
13570 Wright Circle
Tampa, FL 33626

Re: Payment for Anodyne

Dear Sirs,

Here in Eureka, Montana we have a small outpatient clinic. We have been using an infrared anodyne product for approximately 20 months. We have seen many patients with diabetic neuropathy and insensate feet in the past 20 months. We treat with anodyne therapy for 30 minutes three times a week here in the clinic. When successful, they proceed on to receive a home unit.

For diabetic neuropathy we have had some good success stories. I know we have a small population here, but we have at least two to three patients using our anodyne therapy system on a weekly basis. We are very happy with this system and the patients are very grateful to have improvement in sensation in their feet.

Overall, I feel Medicare has not only responsibility to continue this therapeutic procedure, but in the long run could be saving a lot of money because of the people who regain sensation, have less wounds and, in general, fewer medical bills due to foot care.

Thank you for your consideration of this matter. I hope you will reconsider your stand and continue to support anodyne treatments.

Sincerely,



F. R. Haidle, Physical Therapist,
Member, APTA

FRH/dd



August 8, 2006

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Tampa, Florida 33626

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Thank you for your attention to this letter. It is greatly appreciated.

Sincerely,

Donna Washington
Systems Administrator

MDM/btr

Dr. Daniel T. Wagner, R.Ph., MBA, Pharm.D.
Nutri-farmacy
2506 Wildwood Road, P.O. Box 238
Wildwood, PA 15091
(412) 486-4588 fax: (412) 486-0246
Dtwmedi@aol.com web: www.nutrifarmacy.com

August 3, 2006

Medicare NCD
Comments
Anodyne Therapy
13570 Wright Circle, Tampa, FL. 33626

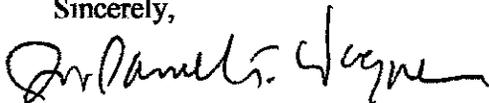
Dear Medicare:

I am writing to inform you of the clinical relevance of the Anodyne Therapy System in my practice. I have a clinic near Pittsburgh, PA., and have been treating patients with diabetic and peripheral neuropathy for three years. I can say without hesitation that the results have been outstanding and many of my patients have benefited by complementing drug therapy and nutrition with the Anodyne system.

I have documented cases in which patients reported a 50 to 75 percent decrease in pain, numbness, and inflammation after receiving 6-12 Anodyne treatments. These patients all had better quality of life outcomes. One recent patient (a diabetic on insulin) was having great difficulty feeling the brake pedal on his car, and he was forced to drive his wife back and forth to the doctor for her particular health problems. He was worried he would have to give up driving a car. After 6 treatments he reported that he felt the brake pedal again, and was much more comfortable driving.

I would professionally recommend that you consider keeping payments intact for doctors performing Anodyne therapy for Medicare patients. This therapy has proven it worth and effectiveness.

Thank you,
Sincerely,



Mainstream Physical Therapy, L.L.C.

The Cypress Lake Professional Center

9371 Cypress Lake Drive #20
Fort Myers, FL. 33919

(239)415-2595
fax: (239)415-2597

August 1st, 2006

To whom it may concern:

This letter is in response to the Medicare non-coverage draft policy for infrared therapy devices. I am a physical therapist currently operating a freestanding clinic in Fort Myers, Florida. During the past seven months, we have used our infrared light unit for more than 220 visits. This comprises between 20 and 30 patients. Over this time, we have seen significant improvement in safety, falls avoidance, balance, sleeping ability, and pain.

The vast majority of these patients exhibited neuropathic symptoms, and the vast majority additionally had diabetes. It is my best estimate that roughly 75% of these patients show clinically significant improvement in their neuropathic pain and balance abilities. Most of them also have clinically documented sensation improvement, and is directly leads to improved activities of daily living.

We have seen no significant negative effects from infrared used during any treatment over the past 2 1/2 years.

At this time, infrared light is the only intervention that has been clinically shown to reverse the effects of decreased blood flow as it relates to neuropathy and pain. Therefore, non-coverage by Medicare will significantly adversely affect patient access to appropriate medical care. In many cases, this is the only intervention that has worked with this patient population.

Therefore, it is my professional opinion that Medicare should continue to cover monochromatic infrared energy for both diabetic and non-diabetic peripheral neuropathy.

Sincerely,



R. Wade Stephan, MSM, MPT

Advanced Physical Therapy Center, INC.

999 Summer Street, Stamford, CT 06905-5513
 203.359.8326 • Fax 203.352.1912
 www.AdvancedPTC.com

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Dave Nebiolo, DPT, MS
*Orthopedics
 Golf Instructor*

Cindy Potter
Office Manager

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Additionally we assessed pain with an 11-pt visual analog scale. Three patients had a **30 – 40% decrease in pain** after the testing period and two patients had no complaint of pain. Finally we assessed sensation via the monofilament testing. Subjects demonstrated an **increase in sensation of 20 – 80%** when comparing initial evaluation to discharge evaluation.

As you can see, the infrared light therapy modality has dramatically improved our patients' quality of life and lowered their risk of injury. They have demonstrated increased balance, increased gait and increased sensation after a trial of the modality. Subjectively, they have complained of less pain, increased balance and increased ability to perform home and work ADL's. Therefore, we ask that you reconsider the non-coverage draft policy for infrared therapy devices.

July 28, 2006

Stephen Wright, M.D.
5050 N Clinton St
Ft. Wayne, IN 46825

Re: Anodyne Treatment Update

Dear Dr. Wright:

In September of 2005 Community Memorial Hospital became an Anodyne Therapy Neuropathy Care Center. Anodyne Therapy consists of monochromatic infrared light therapy used to treat diabetic peripheral neuropathy and wounds.

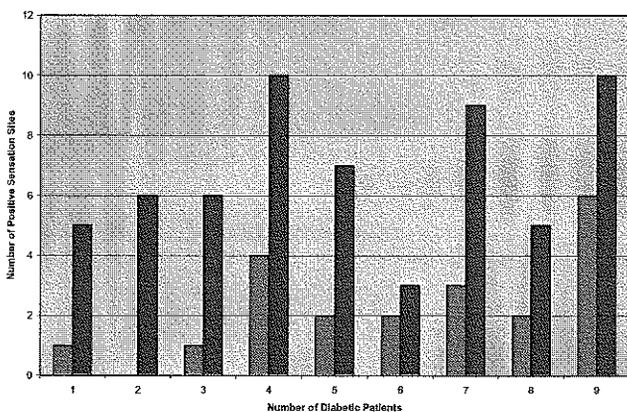
Our studies over the past nine months reflect the success of national studies. These studies show that Anodyne treatment is proven to reduce pain, restore sensation, and improve gait and balance, as well as, improve the general well-being of the majority of patients suffering from diabetic peripheral neuropathy. The treatment has also shown dramatic success in diabetic wound care due to the increased circulation at the site.

Our **greatest results** have been with patients that are **true diabetics versus having neuropathy** from a different source. The following results are based on pre and post testing of nine diabetic patients receiving Anodyne treatments.

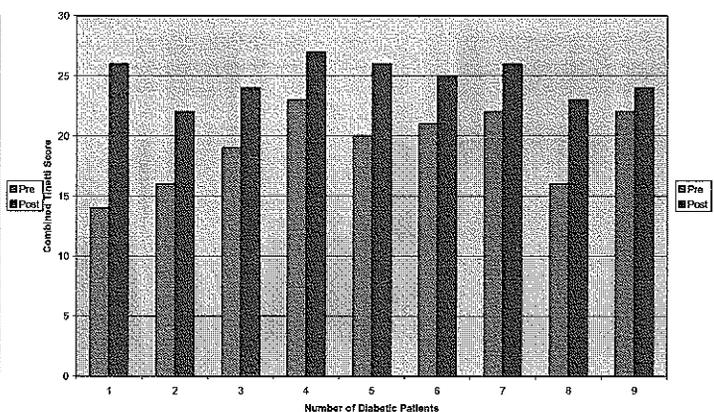
Patient visits range from eleven to twenty-four with the average number of treatments being fifteen.

*"I can't say enough about Anodyne Therapy. I have used it on three wounds over the last 2 years, and it has healed them completely without even a scar. It has also taken all the pain and swelling about of my feet. I am so thankful for this procedure. I only wish more people could try it."
CMH Anodyne Patient*

Monofilament Testing



Tinetti Gait and Balance Testing



The above results are from nine, true diabetic, patients. Monofilament test shows substantial improvement (50% and higher) in sensation in 56% of patients, 30-40% improvement in 34% of patients and 10% improvement in sensation in one patient.

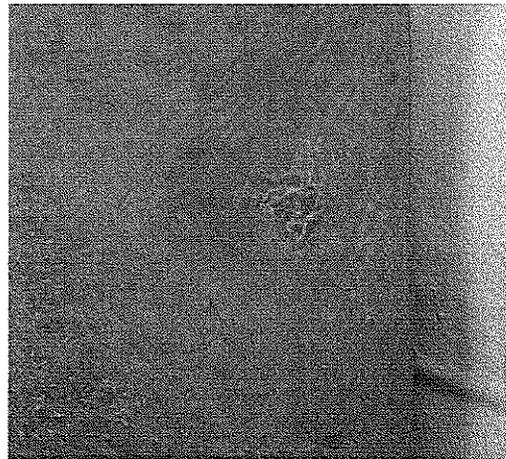
The Tinetti test reveals balance improvement ranging from 7% to 43% with the average improvement being 20%.

Amazing success has also been achieved with regards to **wound treatment**. The following before/after photos are from a patient who presented with a large open wound measuring 5 cm across and 3.4 cm, top to bottom. The wound was .8 cm deep. A plastic surgeon recommended skin grafting; however, the patient opted to use Anodyne Therapy.

The first photo below was taken following 10 treatments; the red ring around the open wound indicates the original size of the wound. The photo on the right shows nearly complete wound closure after just 23 treatments.



The smaller wound measured 1 cm across and .2 cm deep. The photo on the left is following 10 treatments; the photo on the right shows complete closure with good skin integrity and no scarring following just 14 treatments.



No other therapy or medication was used to treat either wound. If you have any questions/comments about this study, please contact one of the therapists below at 419-542-5680. Please keep us in mind when determining the best treatment course for your diabetic patients.

Sincerely,

Camie Stallbaum, P.T.

Sadie Hullinger, P.T. A.

Vicki Gatchell, P.T.

Tiffanie Baird, P.T.A.

Ankle and Foot Specialty ClinicsSteven L. Sheridan, DPM

416 Woodland Drive

Sandusky, MI 48471

Phone: (810) 414-3338

Fax: (810) 648-8883

8/10/06

Dear Medicare,

I have been referring my diabetic patients with neuropathy to a physical therapy department locally. I have seen amazing results and it would be a severe blow to our treatment option for diabetic neuropathy if this became a cash only option.

Please reconsider the complete loss of availability to my patients. Lower reimbursement or whatever it takes.

Thank you for your time.

Sincerely,



CARROLL COUNTY MEMORIAL HOSPITAL
Rehab Department
1502 North Jefferson
Carrollton, MO 64633
660-542-1664

8/08/06

MEDICARE NCD Comments

Dear Sirs:

I am writing concerning the proposed non-coverage policy for Anodyne Therapy and Anodyne Home Systems. As a licensed physical therapy assistant, I have found that Anodyne Therapy has been extremely successful in treating diabetic neuropathy by producing improved sensation and decreased pain allowing better range of motion and gait. These patients that have received Anodyne Therapy have become safer ambulators, more active people and overall achieve a better level of health than prior to the Anodyne treatment.

We have been extremely pleased with the outcome of the Anodyne product and we have case studies that we can produce concerning the outcome and the reduction of pain. Most out patients would not be inclined to involve themselves with a home unit if they did not feel that they needed it.

Please reconsider the proposal for non-coverage for infrared therapy because it has been instrumental in pain control and improvement in patient function.

Sincerely,

Justina Schuchmann
PTA

HENDERSONVILLE PODIATRY
RUSSELL J. BARONE, DPM, PA
600 FIFTH AVENUE WEST
HENDERSONVILLE, NC 28739

ESTABLISHED 1980
HENPOD@BRINET.COM

PHONE: (828) 697-1343
FAX: (828) 697-3224

August 8, 2006

Dear Sir:

It would be a disservice to the public should Medicare decide to issue a Non-Coverage Draft Policy for Infrared Therapy Devices.

My office has treated more than 253 patients with neuropathy with the Anodyne Therapy System. It is my opinion that more than 70% of them have exhibited improvement in their neuropathic symptoms.

During the 3 years that I have been using Anodyne Therapy System, I have not had any issues with patient safety. Before the first time the device was used on one of my patients, I tried it on myself and was not able to detect any potential for harm.

Should you choose to not cover infrared therapy devices under Medicare, many suffering patients will have no hope to the relief of their symptoms. Many of the patients who have tried Anodyne therapy had already exhausted alternative treatments including cream and oral medications to relieve their neuropathic pain and discomfort. Further, there will be an increased chance of ulceration and potential amputation should we continue to allow patients to walk around without any feeling in their feet.

I strongly recommed that you reconsider your coverage of infrared therapy system. I would be very dissapointed should you choose to not cover this service.

Sincerely,


Russell J. Barone



Coosa Medical Group

an affiliate of Coosa Clinics

August 8, 2006

Medicare NCD
Comments Anodyne Therapy LLC
13570 Wright Circle
Tampa, FL 33626
FAX: 866-314-1842

Dear Medicare Advisors:

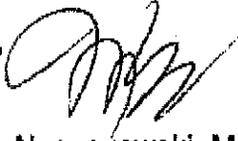
I have been a neurologist now for 16 years, and have treated peripheral neuropathy as a major component of my practice. I would like to voice my opinion regarding anodyne therapy. It is my experience that anodyne therapy is an effective treatment for many of our patients. As you may recall, prior to anodyne therapy, Trental was a common medical treatment trial, with the idea that lowering red blood cell viscosity could promote increased oxygen flow to the vasa nervorum and improve neuropathic symptoms. In my experience, Trental was helpful in about 20% of patients. The fact that Trental was effective speaks for the fact that improvement in the microcirculation is advantageous in both diabetic and nondiabetic neuropathy.

Our anodyne therapy center has results similar to the literature, in that we find that 70% of our diabetic neuropathy patients show improvement, and approximately 50-60% of nondiabetic neuropathy patients also find benefit. Many of these patients have known peripheral vascular disease. Trental and anodyne therapies represent the only interventions to improve circulation in the microvasculature. Anodyne therapy is vastly superior compared to Trental. The advantages of anodyne therapy is that we are not having to deal with any drug interactions, and that proper usage of this treatment brings great emphasis onto the overall patient's individual responsibility for foot care, both in monitoring the feet, as well as proper foot exercises and massage. I hope that Medicare will consider strongly coverage for this important treatment. Clinically our patients have benefited. This benefit is both direct in a reduction of symptoms and a reliance on medications, such as sleeping aids, to promote sleep despite the neuropathic symptoms. We see improvement in these patients' sleep and also in their gait. Even a 20% improvement in the patient's ability to sense their feet will reduce falls. I personally feel that by a reduction in sleep aids, because the patient is more comfortable, reduces the risk of hip fractures in our elderly population in particular. The indirect benefits of reduction in medications and improved sleep result in greater safety for

Medicare NCD
Comments Anodyne Therapy LLC
Page 2

our patients. I greatly appreciate the chance to voice my thoughts, and hope that Medicare will strongly consider support of this treatment.

Sincerely,



William K. Naguszewski, M.D.
WKN/mht

DOT: 08/09/06

KEYSTONE



Orthopedic Specialists, s.c.

Martin R. Hall, M.D., S.C. ■ Mark K. Chang, M.D. ■ Daniel T. Weber, M.D. ■ Nicholas Angelopoulos, D.O.
Phillip Narcissi, D.P.M. ■ John Kalec, M.D.

August 9, 2006

Dear Medicare policy makers:

I am writing this letter to state that it is my professional medical opinion that anodyne treatment is a necessary treatment option in the treatment of neuropathy. I have referred and even treated patients myself with this device over the past several years and state that approximately 80 to 85% of my patient's had 20 to 30% relief from their neuropathy symptoms as well as a complete halt to the progression of their disease. I believe cost efficient wise this is a great treatment because the alternative is Lyrica or Neurontin which I think patients would have to take daily for the rest of their lives. Please note that anodyne care if typically done in 15 to 18 visits. In addition, unlike internal medication the safety of the anodyne is overwhelming. The complications or risks of using this noninvasive treatment are next to none.

Therefore please reconsider your decision to remove anodyne therapy from your Medicare coverage. Again once you consider the cost efficiency, safety and long-term results and efficacy I believe that this treatment should be a necessity for Medicare. Thank you.

Sincerely,

Phillip D. Narcissi, D.P.M.
PN:jk