Anodyne Therapy AHM

Clinical Indications

- **Infrared Coagulation** is considered medically necessary for **ALL** of the following
    - Patients with grade I or grade II internal hemorrhoids that is painful or persistently bleeding. (Grade I- Bleeding without prolapsed; Grade II- Prolapsed with spontaneous reduction)
- Treatment with low-level infrared light (infrared therapy, Anodyne Therapy System) is considered experimental and investigational for the treatment of acne, Bell's Palsy, central nervous system injuries, chronic non-healing wounds, diabetic macular edema, diabetic peripheral neuropathy, ischemic stroke, lymphedema, neck pain, osteoarthritis, parkinson's disease, retinal degeneration, the treatment of back (lumbar and thoracic) pain, stroke and all other indications (except for grade I and II internal hemorrhoids) because of a lack of adequate evidence in the peer-reviewed published medical literature regarding the effectiveness of infrared therapy for these indications [A]
- Infrared glove (e.g. the Prolotex Therapy Glove) is considered investigational for the treatment of Raynaud's syndrome and all other indications because its effectiveness has not been established.
- Low-level infrared light (infrared therapy, Anodyne Therapy System) is considered experimental and investigational.

Evidence Summary

Background

- Low-level infrared therapy is a type of low-energy laser that uses light in the infrared spectrum. The Anodyne Therapy System is a type of low-level infrared therapy, developed by Integrated Systems Physiology Inc. of Aurora, CO, that has been promoted for augmenting wound healing, for reversing the symptoms of peripheral neuropathy in people with diabetes, and for treating lymphedema. The manufacturer states that the Anodyne Therapy System increases circulation and reduces pain by increasing the release of nitric oxide.
- Several meta-analyses have examined the evidence supporting the use of low-level (cold) lasers, including low-level infrared lasers, for treatment of chronic non-healing wounds. These meta-analyses are unanimous in concluding that there is insufficient evidence to

support low-level laser in the treatment of chronic venous ulcers or other chronic non-healing wounds.

- There is no evidence that infrared light therapy is any more effective than other heat modalities in the symptomatic relief of musculoskeletal pain. Glasgow (2001) reported on the results of a randomized controlled clinical trial of low-level infrared therapy in 24 subjects with experimentally induced muscle soreness, and found no significant differences between treatment and placebo groups.
- There are no published studies of the effectiveness of low-level infrared therapy for treatment of diabetic peripheral neuropathy. The case series presented by the manufacturer of the Anodyne System on its web site have not been published in a peer-reviewed medical journal.
- Finally, there is no evidence in the published peer-reviewed medical literature on the effectiveness of infrared therapy for the treatment of lymphedema. The Canadian Coordinating Office of Health Technology Assessment (2002) found that "[t]here is little high quality controlled clinical trial evidence for these therapies."
- In a randomized, placebo-controlled study, Leonard et al (2004) examined whether treatments with the Anodyne Therapy System (ATS) would decrease pain and/or improve sensation diminished due to diabetic peripheral neuropathy (DPN). Tests involved the use of the 5.07 and 6.65 Semmes Weinstein monofilament (SWM) and a modified Michigan Neuropathy Screening Instrument (MNSI). Twenty-seven patients, 9 of whom were insensitive to the 6.65 SWM and 18, who were sensitive to this filament but insensitive to the 5.07 SWM, were studied. Each lower extremity was treated for 2 weeks with sham or active ATS, and then both received active treatments for an additional 2 weeks. The group of 18 patients who could sense the 6.65 SWM but were insensitive to the 5.07 SWM at baseline obtained a significant decrease in the number of sites insensate after both 6 and 12 active treatments ($p < 0.02$ and 0.001). Sham treatments did not improve sensitivity to the SWM, but subsequent active treatments did ($p < 0.002$). The MNSI measures of neuropathic symptoms decreased significantly (from 4.7 to 3.1; $p < 0.001$). Pain reported on the 10-point visual analog scale (VAS) decreased progressively from 4.2 at entry to 3.2 after 6 treatments and to 2.3 after 12 treatments (both $p < 0.03$). At entry, 90 % of subjects reported substantial balance impairment; after treatment, this decreased to 17 %. However, among the group of 9 patients with greater sensory impairment measured by insensitivity to the 6.65 SWM at baseline, improvements in sensation, neuropathic symptoms, and pain reduction were not significant. The authors concluded that ATS treatments improved sensation in the feet of subjects with DPN, improved balance, and reduced pain.
- There are a few drawbacks in this study. They include the small size of the study, and that it involved a single investigator group, arguing for the need to replicate this study. There is also no information about whether the improvements were durable. Furthermore, although the results are encouraging, more discreet quantitative sensory tests would be helpful in determining the exact degree of sensory improvement experienced after the administration of ATS treatments.
- Bhardwaj, et al. (2005) stated that an evolving understanding of laser-tissue interactions involving Propionibacterium acnes-produced porphyrins, and the development of infrared

non-ablative lasers to target sebaceous glands, has lead to the development of an escalating number of laser, light and radiofrequency devices for acne. Used as monotherapy or in combination, these devices are showing promise as a method to clear acne in a convenient, non-invasive manner, though there remains a clear need for long-term data and randomized, blinded studies.

- Chow and Barnsley (2005) examined the effectiveness of low-level laser therapy (LLLT) in the treatment of neck pain through systematically reviewing the literature. A search of computerized bibliographic databases covering medicine, physiotherapy, allied health, complementary medicine, and biological sciences was undertaken from date of inception until February 2004 for randomized controlled trials (RCTs) of LLLT for neck pain. A comprehensive list of search terms was applied and explicit inclusion criteria were developed a priori. A total of 20 studies were identified, 5 of which met the inclusion criteria. Significant positive effects were reported in 4 of 5 trials in which infrared wavelengths (lambda = 780, 810-830, 904, 1,064 nm) were used. Heterogeneity in outcome measures, results reporting, doses, and laser parameters precluded formal meta-analysis. Effect sizes could be calculated for only 2 of the studies. The authors concluded that this review provides limited evidence from 1 RCT for the use of infrared laser for the treatment of acute neck pain (n = 71) and chronic neck pain from 4 RCTs (n = 202). They noted that larger studies are needed to confirm the positive findings, and determine the most effective laser parameters, sites and modes of application.
- In a randomized controlled crossover study, Stange-Rezende et al (2006) examined the effect of infrared radiation of a tiled stove on patients with hand osteoarthritis (OA). A total of 45 patients with hand OA were randomly assigned to two groups: (i) group A -- [first 3 hours spent 3 times a week during 3 weeks in a heated tiled stove room ('Stove Period') and after 2 weeks without treatment this group was observed for another 3 weeks ('control period')]; and (ii) group B (first assigned to the control period and the stove period following the treatment-free period). Assessments included the VAS for general pain, pain in the hands, and global hand function, grip strength, the Moberg Picking-up Test (MPUT), the Australian/Canadian Osteoarthritis Hand Index (AUSCAN), and the Medical Outcomes Study (MOS) 36-item Short-Form Health Status Survey (SF-36). A total of 14 (31 %) patients improved on the VAS for general pain at the end of the tiled stove period as compared to 10 patients (22 %) during the control period (p = 0.314, chi2-test). The AUSCAN pain domain showed a significant improvement after the tiled stove period (p = 0.034). Others pain parameters analyzed (VAS for pain in hands and SF-36 bodily pain) showed moderate but not significant improvement (p = 0.682 and p = 0.237, respectively) compared to the control period. The authors concluded that this study did not prove positive effects of the tiled stove exposure, although the numerical improvement in all pain measures suggests some possible positive effects on this symptom of hand OA.
- Lampl and colleagues (2007) assessed the safety and effectiveness of the NeuroThera Laser System to improve the 90-day outcomes in ischemic stroke patients treated within 24 hours from stroke onset. The NeuroThera Laser System therapeutic approach involves use of infrared laser technology and has shown beneficial effects in animal models of ischemic stroke. A total of 120 ischemic stroke patients were randomized in a 2:1 ratio (n

= 79 patients in the active treatment group and n = 41 in the placebo control group). Only patients with baseline stroke severity measured by National Institutes of Health Stroke Scale (NIHSS) scores of 7 to 22 were included. Patients who received tissue plasminogen activator were excluded. Outcome measures were the patients' scores on the NIHSS, modified Rankin Scale (mRS), Barthel Index, and Glasgow Outcome Scale at 90 days after treatment. The primary outcome measure was successful treatment, documented by NIHSS. This was defined as a complete recovery at day 90 (NIHSS 0 to 1), or a decrease in NIHSS score of at least 9 points (day 90 versus baseline), and was tested as a binary measure (bNIH). Secondary outcome measures included mRS, Barthel Index, and Glasgow Outcome Scale. Primary statistical analyses were performed with the Cochran-Mantel-Haenszel rank test, stratified by baseline NIHSS score or by time to treatment for the bNIH and mRS. Logistic regression analyses were conducted to confirm the results. Mean time to treatment was greater than 16 hours (median time to treatment 18 hours for active and 17 hours for control). Time to treatment ranged from 2 to 24 hours. More patients (70 %) in the active treatment group had successful outcomes than did controls (51 %), as measured prospectively on the bNIH ($p = 0.035$ stratified by severity and time to treatment; $p = 0.048$ stratified only by severity). Similarly, more patients (59 %) had successful outcomes than did controls (44 %) as measured at 90 days as a binary mRS score of 0 to 2 ($p = 0.034$ stratified by severity and time to treatment; $p = 0.043$ stratified only by severity). Also, more patients in the active treatment group had successful outcomes than controls as measured by the change in mean NIHSS score from baseline to 90 days ($p = 0.021$ stratified by time to treatment) and the full mRS ("shift in Rankin") score ($p = 0.020$ stratified by severity and time to treatment; $p = 0.026$ stratified only by severity). The prevalence odds ratio for bNIH was 1.40 (95 % CI, 1.01 to 1.93) and for binary mRS was 1.38 (95 % CI, 1.03 to 1.83), controlling for baseline severity. Similar results held for the Barthel Index and Glasgow Outcome Scale. Mortality rates and serious adverse events (SAEs) did not differ significantly (8.9 % and 25.3 % for active 9.8 % and 36.6 % for control, respectively, for mortality and SAEs). The authors concluded that the NEST-1 study indicated that infrared laser therapy has shown initial safety and effectiveness for the treatment of ischemic stroke in humans when initiated within 24 hours of stroke onset. They stated that a larger confirmatory trial to demonstrate safety and effectiveness is warranted.

- A decision memorandum from the Centers for Medicare and Medicaid Services (2006) has concluded that “there is sufficient evidence to conclude that the use of infrared devices is not reasonable and necessary for treatment of Medicare beneficiaries for diabetic and non-diabetic peripheral sensory neuropathy, wounds and ulcers, and similar related conditions, including symptoms such as pain arising from these conditions.”
- In a double-blind, sham-controlled, randomized study, Lavery et al (2008) examined the effectiveness of Anodyne monochromatic infrared energy (MIRE) in-home treatments over a 90-day period to improve peripheral sensation and self-reported quality of life (QOL) in individuals with diabetes. A total of 69 individuals with diabetes and a vibration perception threshold (VPT) between 20 and 45 V were randomly assigned to two treatment groups: (i) active or (ii) sham treatment. Sixty patients (120 limbs) completed the study. Anodyne units were used at home every day for 40 minutes for 90

days. Nerve conduction velocities, VPT, Semmes-Weinstein monofilaments (SWM) (4-, 10-, 26-, and 60-g monofilaments), the Michigan Neuropathy Screening Instrument (MNSI), a 10-cm visual analog pain scale, and a neuropathy-specific QOL instrument were measured. A nested repeated-measures multiple ANOVA design was employed. Two sites (great toe and 5th metatarsal) were tested on both the left and right feet of each patient, so two feet were nested within each patient and two sites were nested within each foot. To analyze the ordinal SWM scores, a non-parametric factorial analysis for longitudinal data was used. There were no significant differences in measures for QOL, MNSI, VPT, SWM, or nerve conduction velocities in active or sham treatment groups ($p > 0.05$). The authors concluded that Anodyne MIRE therapy was no more effective than sham therapy in the treatment of sensory neuropathy in individuals with diabetes.

- In a controlled, double-blind, randomized clinical study, Franzen-Korzendorfer et al (2008) examined the effect of monochromatic infrared energy on transcutaneous oxygen measurements and protective sensation in patients with diabetes and a loss of protective sensation. A total of 18 adults (12 men, 6 women; mean age of 65 +/-13 years, range of 39 to 86 years) with diabetes and loss of protective sensation were recruited using convenience sampling methods. All patients served as their own control. Pre- and post-treatment tests assessed sensation, pain, and transcutaneous oxygen measurements on 2 sites/foot. Subjects underwent a series of 30-min monochromatic infrared energy treatments (1 foot active treatment, 1 foot sham). Monochromatic infrared energy was delivered at the manufacturer pre-set level of energy of 1.5 J/cm(2)/min at a wavelength of 890 nm; sham units delivered no energy. Scores were analyzed using paired t-tests and Pearson's correlation coefficient. No significant differences were observed between active and sham treatments for transcutaneous oxygen values, pain, or sensation. Both active and sham monochromatic infrared energy-treated feet had significantly improved sensation when compared to pretest baseline scores ($p < 0.05$). No statistical relationship was found between transcutaneous oxygen and sensation. The authors concluded that these findings did not demonstrate any effects of monochromatic infrared energy treatment on transcutaneous oxygen measurements, pain, or sensation in adults with diabetes and loss of protective sensation.
- Ko and Berbrayer (2002) determined the effectiveness of ceramic impregnated gloves in the treatment of Raynaud's syndrome. A total of 93 patients met the "Pal" criteria for Raynaud's syndrome. Treatment period of 3 months with use of ceramic-impregnated gloves was adopted. Primary end points included pain VAS ratings and diary; disabilities of the arm, shoulder, hand (DASH) questionnaire; Jamar grip strength; and Purdue board test of hand dexterity. Secondary end points were infrared skin temperature measurements; 7-point Likert scale rating of treatment. In 60 participants with complete data, improvements were noted in the VAS rating ($p = 0.001$), DASH score ($p = 0.001$), Jamar grip strength ($p = 0.002$), infrared skin fingertip temperature ($p = 0.003$), Purdue hand dexterity test ($p = 0.0001$) and the Likert scale ($p = 0.001$) with ceramic gloves over the placebo cotton gloves.
- The authors concluded that the ceramic-impregnated "thermoflow" gloves have a clinically important effect in Raynaud's syndrome. The findings of this study need to be validated by well-designed studies with larger number of patients and longer follow-ups.

- Fitzgerald et al (2013) stated that abstract Irradiation in the red/near-infrared spectrum (R/NIR, 630 to 1,000 nm) has been used to treat a wide range of clinical conditions, including disorders of the central nervous system (CNS), with several clinical trials currently underway for stroke and macular degeneration. However, R/NIR irradiation therapy (R/NIR-IT) has not been widely adopted in clinical practice for CNS injury or disease for a number of reasons, which include; (i) the mechanism(s) of action and implications of penetration have not been thoroughly addressed, (ii) the large range of treatment intensities, wavelengths and devices that have been assessed make comparisons difficult, and (iii) a consensus paradigm for treatment has not yet emerged. Furthermore, the lack of consistent positive outcomes in RCTs, perhaps due to sub-optimal treatment regimens, has contributed to skepticism.
- These researchers provided a balanced summary of outcomes described in the literature regarding treatment modalities and efficacy of R/NIR-IT for injury and disease in the CNS. They have addressed the important issues of specification of treatment parameters, penetration of R/NIR irradiation to CNS tissues and mechanism(s), and provided the necessary detail to demonstrate the potential of R/NIR-IT for the treatment of retinal degeneration, damage to white matter tracts of the CNS, stroke and Parkinson's disease.
- Vujosevic et al (2013) reviewed the most important metabolic effects and clinical safety data of sub-threshold micropulse diode laser (D-MPL) in diabetic macular edema (DME). The MPL treatment does not damage the retina and is selectively absorbed by the retinal pigment epithelium (RPE). Micropulse diode laser stimulates secretion of different protective cytokines by the RPE. No visible laser spots on the retina were noted on any fundus image modality in different studies, and there were no changes of the outer retina integrity. Mean central retinal sensitivity (RS) increased in D-MPL group compared to standard Early Treatment Diabetic Retinopathy Study (ETDRS) photocoagulation group. The authors concluded that MPL is a new, promising treatment option in DME, with both infrared and yellow wavelengths using the less aggressive duty cycle (5 %) and fixed power parameters.
- Infrared Coagulation for the Treatment of Hemorrhoids:Infrared coagulation is one of the several non-surgical outpatient therapies in treating hemorrhoids. Linares et al (2001) examined the effectiveness of rubber band ligation (RBL) and infrared photocoagulation (IRC) in treating internal hemorrhoids in 358 patients with a total of 817 hemorrhoid. There was a follow-up period of 36 months. Two hundred ninety five of 358 patients were treated with RBL (82.4 %), this treatment being effective in 98 % of the patients after 180 days and very good after 36 months. There were 6/295 relapses at 36 months (2 %). All minor and major complications were observed within the first 15 days of treatment: rectal tenesmus in 96/295 patients (32.5 %), mild anal pain in 115/295 (38.9 %), self-limited and mild bleeding after the detachment of the bands in 30/295 (10 %), and febricula in one patient.
- Sixty-three of 358 patients were treated with IRC (17.6 %). In this group, relapses were observed in 6/63 patients (9.5 %) at 36 months, all of them with grade III hemorrhoids that required additional treatment with RBL. All the complications (inherent to the technique) were observed within the first days: mild anal pain in 40/63 patients (63.4 %) and mild bleeding in 1/63 (1.6 %). The treatment with RBL or IRC depended on the

number of hemorrhoids and the hemorrhoidal grade. No significant differences were found regarding the effectiveness between RBL and IRC for the treatment of grade I-II hemorrhoids, while RBL was more effective for grade III and IV hemorrhoids ($p < 0.05$). The authors concluded that RBL and IRC should be considered as a good treatment for all grades of hemorrhoids, due to its effectiveness, its cost-benefit and its small short-term and long-term morbidity.

- In a randomized study, Gupta (2003) compared infrared coagulation and rubber band ligation in treating patients with early stages of hemorrhoids. One hundred patients with second degree bleeding piles were randomized prospectively to either rubber band ligation (n = 54) or infrared coagulation (n = 46). Parameters measured included post-operative discomfort and pain, time to return to work, relief in incidence of bleeding, and recurrence rate. Post-operative pain during the first week was more intense in the band ligation group (2 to 5 versus 0 to 3 on a VAS). Post-defecation pain was more intense with band ligation and so was rectal tenesmus ($p = 0.0059$). The patients in the infrared coagulation group resumed their duties earlier (2 versus 4 days, $p = 0.03$), but also had a higher recurrence or failure rate ($p = 0.03$).
- The authors concluded that band ligation, although more effective in controlling symptoms and obliterating hemorrhoids, is associated with more pain and discomfort to the patient. As infrared coagulation can be conveniently repeated in case of recurrence, it could be considered to be a suitable alternative office procedure for the treatment of early stage hemorrhoids.
- The American Gastroenterological Association's technical review on the diagnosis and treatment of hemorrhoids (Madoff and Fleshman, 2004) stated that 1st degree and 2nd degree hemorrhoids (i.e., Grade I and Grade II hemorrhoids) can be treated with non-operative therapies such as infrared photocoagulation. Surgery is generally reserved for individuals who have large 3rd degree or 4th degree hemorrhoids, acutely incarcerated and thrombosed hemorrhoids, hemorrhoids with an extensive and symptomatic external component, or individuals who have undergone less aggressive therapy with poor results.

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Footnotes

[A] Infrared light treatment is considered medically necessary as a heat modality in physical therapy

Codes

CPT® or HCPCS: 46930, 97026, E0221