Name of Policy:
Laser Treatment of Active Acne

Policy #: 394  Latest Review Date: December 2009
Category: Surgery  Policy Grade: B

Background:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:
1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Description of Procedure or Service:
Lasers have been used to treat acne scarring, and may also be useful for active acne. Various types of laser treatments are available, including pulsed and non-pulsed devices, and differing wavelengths of emitted light. It has been reported that lasers may improve active acne by killing propionibacterium acnes (P. acnes) and/or by reducing inflammation.

Acne is a very common disorder of the pilosebaceous follicles that primarily affects adolescents and young adults, and may be classified as inflammatory or noninflammatory. Acne is characterized by comedones, nodules, and eruptions of papules, pustules, and nodulocystic lesions. Lesions are found in areas with the greatest concentration of sebaceous glands, i.e., the face, neck, and upper part of the trunk. The four causal factors of acne are androgen-mediated sebaceous gland hyperplasia and excess sebum production; abnormal follicular keratinization, which results in plugging of the follicles, and comedo formation; proliferation of propionibacterium acnes (P. acnes); and inflammation resulting from the chemoattractant and proinflammatory byproducts of P. acnes. Genetic factors, diet, and stress may also contribute to
the development and severity of acne. Treatment of active acne usually consists of good skin care regimen, benzoyl peroxide, antibiotics, and retinoids. Active acne is distinct from acne scarring, which may occur for tissue damage after inflammatory lesions subside.

Pulsed dye laser has been used in the treatment of acne scarring; however, more recently, lasers have been investigated for the treatment of active inflammatory acne. Laser therapy at various irradiation levels or fluencies (e.g., low-and mid-level irradiation lasers and long-pulse diode lasers) has been used to destroy active acne lesions and enlarged sebaceous glands. Lasers are believed to improve active acne lesions by reducing the presence of P. acnes, which contain porphyrins that are destroyed by inflammatory affects (i.e., red light of 660nm) that may improve active acne. Low fluence pulsed dye lasers are less ablative and purpuric and may be preferred in active acne treatment to limit tissue damage and potential treatment-related scarring. Laser treatment of active acne lesions may also reduce potential acne scarring that can occur in severe cases.

Policy:
Effective for dates of services on or after March 12, 2010:
Laser treatment of active acne does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:
Two systematic reviews of light therapies were identified in the MEDLINE literature search. Both reviews included studies on photodynamic therapy, as well as light and laser therapy. This policy does not discuss the use of photodynamic therapy (PDT). Neither review conducted any pooled analysis of laser treatment studies due to heterogeneity between studies (e.g. different wavelengths of light were used). The two systematic reviews had similar assessments of the literature. Hamilton and colleagues identified ten randomized controlled trials (RCTs) comparing light therapy to placebo and three RCTs comparing light therapy to topical treatment of acne. The authors commented that studies of light therapy tended to be small (all had fewer than 50 participants), of short duration and of variable quality, and few compared light therapy to conventional treatment. They concluded: “our review found only limited or no benefit is given by light therapies alone…Further trials comparing light therapy with usual treatment, using a larger effect size in the power calculations, would be helpful to determine the usefulness of light therapy in treating acne.” The other systematic review by Haederdal and colleagues include 11 RCTs on light treatments (other than photodynamic therapy) and stated that most of the studies had suboptimal methods. For example, few studies described their randomization method and most had large losses to follow-up without intention to treat analysis. The authors state, “Based on the present best available evidence, we conclude that optical treatments with lasers, light
sources and PDT posses the potential to improve inflammatory acne on a short-term basis with the most consistent outcomes for PDT. We recommend that patients are informed of the existing evidence, which denotes that optical treatments for acne today are not included among first-line treatment”. There is no separate conclusion focusing on laser therapy. The systematic reviews identified a number of side effects from optical treatments and these include pain, erythema, edema, crusting, hyperpigmentation, and pustular eruptions.

Key individual RCTs with at least 40 participants are described below:

Seaton and colleagues (2004) reported that low-energy pulsed dye laser therapy has been used, and seems to be a promising alternative that would allow the simultaneous treatment of active acne and acne scarring. Their double-blind RCT for 41 adults with mild to moderate facial inflammatory acne randomized patients to receive a single low fluence pulsed dye laser treatment or sham treatment. At 12 weeks, Leeds acne scores fell from 3.8 to 1.9 in the treatment group and from 3.6 to 3.5 in the control group. The total lesion count fell by 53% and 9% and inflammatory lesion counts fell by 49% and 10% in the laser treatment group and control group, respectively. These results show statistically significant improvements. However, the authors concluded that further studies are needed to clarify the role of phototherapy as a monotherapy or an adjuvant treatment in the current management of acne vulgaris.

Orringer et al., reported on a single-blind split face RCT of 40 patients (aged 13 years or older with a Leeds acne score of two or greater) randomized to receive with one or two sessions of pulsed dye laser treatment (3 J/cm2 fluence) to half of the face with the opposite, non-treated side serving as the control. At 12 weeks, changes in lesions counts (including pustules, comedones, macules, cysts, and papules) and mean Leeds acne scores with not significantly different for the treated versus untreated sides of the face. The authors concluded that”…additional well designed studies are needed before the use of pulse dye laser becomes a part of acne therapy.”

In a later study, Orringer and colleagues reported on a RCT that assessed the efficacy of a 1320-nm laser (CoolTouch II) in 46 patients in a split-face design. Laser treatment was given once every three weeks, with blinded evaluation by a panel of three dermatologists (from photographs taken at 7 and 14 weeks). Thirty patients completed the 14-week assessment (35% dropout); data were carried forward to adjust for subjects who may have dropped out of the study due to lack of effect. The authors reported that the treated side remained unchanged at 0.22 cysts (10 total cysts in 46 subjects) while the untreated side increased from 0.27 to 0.70 cysts. Subjective patient reports (of 37 who completed at least the 7-week assessment; not blinded to treatment) favored the treated side over the control side for a decrease in acne (59%) and oily skin (54%). No differences were found between the treated and un-treated sides in the number of papules, pustules, open comedones, or closed comedones at 14 weeks.

Laheta and colleagues’ study included 45 patients with mild to moderate acne. They were randomly assigned to one of three groups (15 patients per group). Group A received pulsed dye laser therapy (3J/cm2 fluence) every two weeks for six sessions; Group B applied topical treatment with 0.1% tretinoin cream every evening and 5% benzoyl peroxide gel every morning; and Group C underwent chemical peeling using trichloroacetic acid 25%. An assessor blinded to treatment group e4valuated outcomes; 41 patients were included in the analysis. There was no significant difference between groups in the acne severity score (0=no acne to 10=severe acne) at
the end of the three month treatment period. Mean scores with 0.56 ± 0.47 for Group A and 0.65 ± 0.47 for Group B and 0.69 ± 0.50 for Group C (p=0.38). The analysis of disease severity did not adjust for baseline scores, and standard deviations were large due to the small number of participants in each group. The degree of clinical response (marked or moderate) and side effects (trace, mild or moderate) also did not differ significantly between the three groups. The proportion of patients with moderate side effects was 23% in Group A, 15% in Group B and 13% in Group C (overall p-value =0.95).

Due to the small sample sizes of the published trials, lack of long-term follow-up, small number of studies on any particular type of laser and paucity of studies comparing light therapy to standard acne treatments, the evidence is insufficient to draw conclusions on the impact of laser treatments on health outcomes in patients with active acne.

Finally, in 2009, an update from the Global Alliance to Improve Outcomes in Acne Group looked at studies to determine, “Does enough evidence now exist for using lasers and lights to treat inflammatory acne?” The members of the Global Alliance concluded, “That more data are needed before the role of lasers and light treatments in inflammatory acne can be assessed. Before any of these technologies can be viewed as standard treatments for acne, they need to mature and be tested in large, well-designed clinical trials and by experience in normal clinical practice.”

**Key Words:**
Laser, Candela Smoothbeam, CoolTouch, Radiancy ClearTouch, ThermaClear, Aura™, Clearlight, Dermilume, acne vulgaris, YAG laser, pulsed dye laser

**Approved by Governing Bodies:**
A number of laser and focused light devices have received marketing clearance for the treatment of acne via the U.S. Food and Drug Administration’s (FDA’s) 510(k) mechanism. These include lasers that emit light at 1320 nm (Candela Smoothbeam™ and CoolTouch®); intense pulsed light systems, which emit light in the range of 590 to 1200nm (Radiancy ClearTouch™, MED flash ii and Elisped I²PL); pulsed dye lasers (ICN Photonics NLite System); and lasers or high-intensity light devices, which emit violet or blue (around 414 nm) and red (around 633 nm) light (Aura™, Clearlight and Dermilume). The specific indications for these devices vary; Candela Smoothbeam™ is indicated solely for the treatment of acne on the back, others are indicated for the treatment of inflammatory acne or for mild to moderate acne with no location specified. In 2006, a thermal device (ThermaClear™) was cleared for marketing for the “treatment of individual acne pimples in persons with mild to moderate inflammatory acne” in both a practitioner’s office environment and a consumer home-use environment.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
AT&T contracts: No special consideration
FEP: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.
Pre-certification requirements: Not applicable
Pre-determination requirements: Pre-determinations will be performed as a courtesy review at the request of the physician and/or subscriber.

**Coding:**
CPT Codes: 17110-17111 Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettage), of benign lesions other than skin tags or cutaneous vascular lesions

**References:**

**Policy History:**
Medical Policy Group, December 2009 (3)
Medical Policy Administration Committee, January 2010
Available for comment January 26-March 11, 2010

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plans contracts.