Name of Policy:
Pulsed Dye Laser Treatment of Recalcitrant Verrucae

Policy #: 187      Latest Review Date: July 2010
Category: Surgery
Policy Grade: Active Policy but no longer scheduled for regular literature reviews and updates.

Background/Definitions:
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.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
The flashlamp-pumped pulsed dye laser (PDL) produces short pulses of yellow light at short wavelengths (585-600 nm) to induce selective thermal damage to cutaneous vessels. It has been used to treat vascular lesions including port wine stains, hemangiomas, telangiectasias, hypertrophic scars, and warts. The pulsed dye laser has been used as an alternative to surgical excision or carbon dioxide lasers.

The pulsed-dye laser (585 nm) has been used to treat warts by producing selective photothermolysis of dermal blood vessels. There have been several studies with varied clearance rates of warts. There is some debate that different treatment techniques may be responsible for the variable outcomes. Various authors have suggested that paring of the lesion between treatments, using high fluences with stacked pulses at fast pulse repetition rates, and follow up with shorter treatment intervals may improve response rates. The side effects include transient pain and erythema and the sites treated usually heal with minimal or no residual scarring.

The U.S. Food and Drug Administration (FDA) has cleared the pulsed-dye laser for use in treatment of port-wine stains, hemangiomas, telangiectasias, hypertrophic scars and warts.

The newest versions of the pulsed dye lasers have rapid pulse repetition rates (one pulse per second), multiple spot sizes (3, 5, 7, and 10 mm), and require dye changes only every 75,000 pulses. Candela Corporation, Wayland, MA, manufactures a flash-lamp pumped PDL (585 nm).

Policy:
Pulsed dye laser for the treatment of recalcitrant verrucae meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when conventional therapy such as topical chemotherapy, curettage, electrodesiccation, and cryotherapy has failed.

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:
There have been many published reports on the use of the pulsed dye laser to treat recalcitrant verrucae. Some of the reports are summarized below.

Taw, et al (1993), reported on the use of the pulsed dye laser (585 nm) to treat recalcitrant warts. The results showed 28 of 39 patients (72%) were cured after an average of 1.68 treatments.

Kauvar, et al (1995), reported on a layer series, 142 patients, also treated with the pulsed dye laser for recalcitrant warts. The results showed an overall response rate of 74% after one
treatment and 93% after an average of 2.5 treatments with 3 to 9 months follow up. The response rates were 99% for body and extremity warts, 95% for hand warts, 84% for plantar warts, and 83% for periungual warts.

Jacobson, et al (1997), reported on pulsed dye laser therapy to treat 32 patients, 19 with recalcitrant warts and 13 with no prior treatment. All warts were treated an average of 1.72 times. The results showed that 68% of the recalcitrant warts and 47% of the no prior treatment warts were completely cleared.

Ross, et al (1999), reported on 33 patients treated with pulsed dye laser for recalcitrant warts. The results showed a 48% cure rate, which was lower than previous reports.

Kenton-Smith, et al (1999), reported on 28 patients with recalcitrant and simple viral warts treated with pulsed dye laser. The results showed a cure rate of 92% for recalcitrant warts after an average of 2.1 treatments and 75% for simple warts after an average of 1.6 treatments with a mean follow up of 7.2 months.

Robson, et al (2000), reported on a prospective randomized trial of 40 patients comparing pulsed-dye laser (PDL) to conventional therapy (cryotherapy or cantharidin application) in the treatment of warts. The results showed a cure rate of 70% in the conventional therapy group and 66% in the PDL group (not statistically significant). So, the authors concluded that this data suggests that PDL is probably not superior treatment. However, in a follow-up letter to the editor by Kawar and Geronemus, they suggested that different treatment techniques may account for the relatively poor response rate.

Wu, et al (2003), reviewed the records of 44 patients treated with PDL for viral warts. The results showed a 64% cure rate for all areas treated, and 46% cure rate for recalcitrant warts. Also, 25% of patients complained of severe pain during treatment and 36% reported recurrence of warts in weeks to months following treatment.

**July 2008 Update**
Bacelieri and Johnson published an evidence-based review related to the treatment on cutaneous warts. A number of methods of treatments were reviewed including topical salicylic acid, cryotherapy, pulsed dye laser therapy, retinoids, and intrallesional immunotherapy. Regarding the use of pulsed dye laser therapy, Bacelieri and Johnson reported that studies have examined the effectiveness of pulsed dye laser therapy after an average of 2-3 treatments and reported overall cure rates of 48% to 93% for warts located at various sites. One study had a 72% overall clearance rate with the highest being 85.7 for periungual warts, and the lowest clearance rate was 50% for plantar warts. Another study review compared pulsed dye laser therapy with cryotherapy and cantharidin. Of the cryotherapy or cantharidin, 70% demonstrated clearance after two treatments, whereas 66% of the patients treated with pulsed dye laser demonstrated clearance following two treatments. The authors concluded that pulsed dye laser therapy is as effective as conventional therapy.

**July 2010 Update**
In a recent literature search no new studies were identified that would alter the coverage statement of the policy. No further review of this policy is planned.
Key Words:
Pulsed dye laser, verrucae (warts)

Approved by Governing Bodies:
Numerous pulsed dye lasers are FDA approved.

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

ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member’s benefit plan.
Pre-certification/Pre-determination requirements: Not applicable

Coding:
Effective for dates of service on or after January 1, 2007:

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>17000</td>
<td>Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (e.g., actinic keratoses); first lesion</td>
</tr>
<tr>
<td>17003</td>
<td>Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (e.g., actinic keratoses); second through 14 lesions, each (list separately in addition to code for first lesion)</td>
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<tr>
<td>17004</td>
<td>Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (e.g., actinic keratoses); 15 or more lesions</td>
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<tr>
<td>17110</td>
<td>Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), of benign lesions other than skin tags or cutaneous vascular lesions; up to 14 lesions</td>
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<tr>
<td>17111</td>
<td>Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), of benign lesions other than skin tags or cutaneous vascular lesions; 15 or more lesions</td>
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Effective for dates of service on or prior to December 31, 2006:

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<th>CPT</th>
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<tr>
<td>17000</td>
<td>Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), all benign or premalignant lesions (e.g., actinic keratoses) other than skin tags or cutaneous vascular proliferative lesions; first lesion</td>
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<tr>
<td>17003</td>
<td>Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), all benign or premalignant lesions (e.g., actinic keratoses) other than skin tags or cutaneous vascular proliferative lesions; first lesion</td>
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vascular proliferative lesions; second through 14 lesions, each (list separately in addition to code for first lesion)

17004 Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettage), all benign or premalignant lesions (e.g., actinic keratoses) other than skin tags or cutaneous vascular proliferative lesions; 15 or more lesions

17110 Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettage), of flat warts, molluscum contagiosum, or milia; up to 14 lesions

17111 Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettage), of flat warts, molluscum contagiosum, or milia; 15 or more lesions

References:
Policy History:
Medical Policy Group, July 2004 (1)
Medical Policy Administration Committee, August 2004
Available for comment August 11-September 24, 2004
Medical Policy Group, July 2006 (1)
Medical Policy Group, July 2008 (1)
Medical Policy Group, July 2010 (1)

Medical Policy Group, July 1, 2010: Active Policy but no longer scheduled for regular literature reviews and updates.

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 plan contracts.