PORT-WINE STAIN HEMANGIOMA TREATMENT

Policy Number: 2016M0042A  Effective Date: February 1, 2016

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee's specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:

This medical policy describes the treatment of port-wine stains. Port-wine stains are malformed dilated blood vessels in the skin, present at birth and starting as pink macules. If untreated, port-wine stains tend to become darker and thicker over time. They usually occur on the face and neck but can be located elsewhere on the body. Laser therapy is used for eliminating port-wine stains. It is the only method that can destroy the tiny blood vessels in the skin without significantly damaging the skin. The exact type of laser used depends on the person's age and the particular port-wine stain.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS

The state of Minnesota mandates coverage for port-wine stain elimination or maximum feasible treatment of port-wine stains for any covered person who is a Minnesota resident. As in all benefit adjudication, federal and state legislated mandates must be followed.

1. Laser therapy is considered MEDICALLY NECESSARY for the treatment of port-wine stain lesions. Any device utilized for this procedure must have FDA approval specific to the indication, otherwise it will be considered investigational.

2. Indications that are NOT MEDICALLY NECESSARY:
   - Treatment of NON port-wine stain hemangiomas and other vascular abnormalities that is performed primarily to alter or enhance COSMETIC appearance, such as spider veins, spider angiomas, cherry angiomas, facial telangiectasias and strawberry hemangiomas.
   - Flesh color tattooing and cosmetics.
   - Treatments for flat port-wine stains that are considered ineffective, resulting in low success rate outcomes, such as, but not limited to:
     - Dermabrasion
     - X-Ray Treatment
     - Chemical Peel
     - Liquid Nitrogen
     - Skin Grafting
     - Dry Ice
     - CO2 Snow
     - Surgical Excision
     - CO2 laser (far infrared)
     - Nd; YAG laser (near infrared) and argon laser
     - Steroids
   - Laser treatment of port-wine stain in combination with photodynamic therapy or topical angiogenesis inhibitors is considered EXPERIMENTAL AND INVESTIGATIONAL. There is insufficient evidence that lasers combined with photodynamic therapy or topical angiogenesis inhibitors, is superior to laser treatment alone.

Clinical Considerations:

- Complications reported in the reviewed studies of PDL therapy were generally mild and transient. The safety profile is similar regardless of the type of lesion being treated. The most common side
effect is transient hyperpigmentation, which occurs in 1% to 57% of patients. Other complications include hypopigmentation, scarring, swelling, blistering, crusting, and bleeding. In rare instances, pyogenic granulomas can form as a result of PDL therapy.

- Thus, for optimal treatment results and to minimize the risk of pigmentary changes after treatment, the patient should achieve the palest skin possible by avoiding sun exposure and use of a broad-spectrum sunscreen with SPF 50+ for at least 1 month before and after laser treatment.

**BACKGROUND:**

**Port-Wine Stain:** Port-wine stains (PWS) are congenital vascular malformations of the skin that affect approximately 0.3% to 0.5% of newborns; the exact cause is unknown. PWS are chronic lesions characterized by enlarged and dilated venules and capillaries in the superficial dermis; the lesions can extend into deeper vessels of the dermis and subcutaneous tissues. At birth, the lesions typically appear as flat, faint, pink macules. With increasing age, they darken and become raised, red-to-purple nodules and papules in adults. Found most often on the face, neck, arms, or legs; PWS can arise anywhere on the body and vary in size. Due to their potential for disfigurement, PWS can cause negative emotional and social consequences; thus, early treatment is usually recommended to prevent enlargement, to improve the patient’s appearance, and to reduce the likelihood of medical complications. While many different types of treatments have been investigated for PWS, including excision and grafting, dermabrasion, cryotherapy, sclerotherapy, tattooing, irradiation, and laser therapy, no treatment is entirely satisfactory and most have unacceptable side effects, including bleeding, pain, scarring, and risk of malignant transformation.

**Congenital hemangiomas:** Congenital hemangiomas are benign tumors of the vascular endothelium that appear at or shortly after birth, usually within 4 to 6 weeks. They occur in 1% to 3% of newborns and in 10% to 20% of children by 1 year of age; 15% to 30% of infants with lesions have multiple lesions. Hemangiomas are characterized by a 6- to 12-month period of proliferation during which they grow to a size of 2 to 20 centimeters (cm). This is followed by a stationary or plateau period in which there is little change. A period of slow involution, or regression, begins at approximately 15 to 18 months of age and can last for several years. Complete regression occurs in approximately 50% of children by 5 years of age and in approximately 90% of children by 9 years of age. The superficial capillary, or strawberry, hemangioma accounts for approximately 50% to 60% of cases, while deep hemangiomas account for approximately 15%. Mixed hemangiomas, which contain both superficial and deep components, account for approximately 15% to 30% of lesions. Although they are heterogeneous in their appearance, hemangiomas frequently arise as telangiectatic macules or blanched spots, or, rarely, as a small ulceration. They are located on the head or neck in 60% of cases, on the trunk in 25%, and on the extremities in 15%. Despite the fact that most hemangiomas resolve on their own, approximately 50% persist in school-age children and, even after involution, 20% to 40% leave behind residual skin changes. Hemangiomas can be complicated by bleeding, ulceration, or secondary infection, or may be located in areas of the body where they cause functional impairment. Some are potentially life threatening, including hemangiomas that obstruct the respiratory tract. Low-risk hemangiomas are either left untreated or may be treated with intralesional corticosteroid injections, pressure occlusion, laser therapy, cryosurgery, or surgical excision. High-risk lesions, including lesions that are large, potentially disfiguring, lesions in a prognostically poor location, or lesions causing functional impairment or life-threatening complications, are treated with systemic or topical corticosteroids, subcutaneous alpha-2a interferon, laser therapy, surgical excision, or cryosurgery.
Recently, propranolol has become a first-line therapy for hemangiomas. Many different types of treatments have been investigated for hemangiomas and PWS, such as excision and grafting, dermabrasion, cryotherapy, sclerotherapy, tattooing and irradiation. More recently, laser treatment has been used with good results and the least amount of risk and side effects.

The flashlamp-pumped pulsed dye laser (PDL), introduced in 1985, and was developed specifically for the treatment of cutaneous vascular lesions. PDL emits one specific color, or wavelength, of light that can be varied in its intensity and pulse duration. The hemoglobin within dilated or enlarged blood vessels comprising cutaneous vascular lesions preferentially absorbs the energy from the PDL and generates heat, leading to the thermal destruction of the lesion, while sparing normal surrounding tissues.

Pulsed dye laser (PDL) therapy for port-wine stain (PWS) is typically administered during multiple sessions at 4- to 8-week intervals; maximum clearing may take months or, in some cases, more than a year. Laser energy is applied using overlapping pulses and PDL parameters used for treatment of PWS generally are as follows: wavelength of 585 to 600 nanometers (nm); fluences of 4 to 12 joules per centimeter squared (J/cm²); pulse duration of 0.45 to 10 milliseconds (msec); and spot size of 7 to 10 millimeters (mm). A larger spot size generally produces a better outcome, as the laser beam can penetrate deeper into the lesion; however, increasing the spot size may require decreased peak fluences due to laser limitations. Specific parameters may be determined by testing a representative area(s) within the PWS and/or is based on patient age, skin type, lesion thickness, or lesion color. Before treatment begins, the patient’s eyes are covered with a shield and topical or local anesthesia is administered, although some patients require no anesthesia. Infants and young children may require sedation or general anesthesia. While ice may be used for additional anesthesia, cooling devices are now standard for PDLs manufactured by Candela Corporation and Cynosure. These cooling devices permit safe use of significantly higher fluences than in the past, thus enhancing laser efficacy. Treatment time depends on the size and extent of the lesion. Most PWS can only be partially treated at each treatment session. A common and immediate post-treatment effect is hyperpigmentation and bruising that may increase over the following 24 hours and last for up to 2 weeks.

The treatment sessions for hemangiomas are similar to those for PWS. The energy density and number of pulses per treatment depend on patient age, the response to prior treatment, and lesion characteristics such as type, thickness, and location. Current PDL parameters for treatment of superficial or ulcerating hemangiomas are: wavelength of 585 to 595 nm; fluences of 5 to 7.5 J/cm²; pulse duration of 300 to 450 microseconds (ms); spot sizes of 5 to 7 mm; and use of a concomitant cooling device. The entire lesion is treated with minimally overlapping pulses of laser energy with the patient wearing protective eyewear. PDL is not considered an appropriate choice for deep or mixed hemangiomas as the laser cannot penetrate more than 1.2 mm, and the risk of scarring is greater following PDL treatment of hemangioma than PWS. Local or no anesthetic is usually sufficient for treating superficial hemangiomas; however, young patients or those with extensive lesions may require general anesthesia. For hemangiomas, PDL is administered at 4- to 6-week intervals; longer intervals between sessions can result in lesion enlargement. Treatment is generally continued until the lesion resolves or stops responding, the patient or family is satisfied with the treatment response, or superficial proliferation ceases spontaneously. After laser therapy, antibiotic ointment is applied to the treated area to reduce crusting and prevent infection.

PDL therapy is usually performed in the physician’s office or in a clinic. The appropriate equipment for monitoring vital signs and for managing patients under conscious sedation should be available, as well as equipment for emergency cardiopulmonary resuscitation. Standard protocols for personnel and patient protection should be in place to prevent the transmission of infection. Procedures that have intrinsic risks
should be performed in an institutional setting instead of in the physician’s office. Before discharge, all patients who undergo office-based procedures should be monitored in a manner similar to that of hospitalized patients and should receive explicit instructions for postoperative care and follow-up (ASLMS, 2008).

Overall, the literature reflects that pulsed dye laser (PDL) therapy is a safe and effective treatment for port-wine stain (PWS). Despite the availability of PDL therapy and other treatment options for PWS lesions, approximately 30% of lesions are resistant to treatment.

REGULATORY STATUS:

1. U.S. FOOD AND DRUG ADMINISTRATION (FDA):
   Pulsed dye lasers (PDLs) are classified as Class II devices and are considered laser surgical instruments for use in general and plastic surgery and in dermatology.

   Several laser systems have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for a variety of dermatologic indications, including treatment of port-wine stains.

   Approved lasers for this indication include:
   - Candela® pulsed dye laser system (Candela Corp.; Wayland, MA) was approved by the FDA in 1986 for the treatment of cutaneous vascular lesions. Since then, various models from the Candela Corporation have been developed and deemed substantially equivalent by the FDA (CDRH, 2012).
   - Photogenica sv® pulsed dye laser (Cynosure Inc; Westford, MA); approved in November 20, 2002 (K021444).
   - Photogenica VLS-Star® pulsed dye laser (Cynosure Inc; Westford, MA); approved March 13, 2000 (K000490).
   - Cynosure Nd:YAG laser system.
   - Cynergy™ Multiplex Laser (Cynosure), a combined Nd:YAG and pulsed dye laser was approved by the FDA in 2005 for treatment of benign vascular and vascular dependent lesions, including port-wine stains.
   - NLite System (ICN Photonics Ltd.); approved June 4, 2002 (K020729).
   - Lumenis® family of intense pulsed light systems was approved by the FDA in 2003; indications for use include dermatologic applications.
   - NannoLight® intense pulsed light system (Global USA Distribution) was approved by the FDA in 2008.
   - Mediflash3 and Esterflash3 systems (Dermeo) were approved in 2010 for indications specifically including treatment of port-wine stains.

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):
   No National Coverage Determination (NCD) on the use of PDL therapy for treatment of PWS or hemangiomas was identified on the CMS website. Medicare recognizes the use of lasers for many medical indications. Refer to the NCD for Laser Procedures (140.5).

   Local Coverage Determinations (LCDs) exist for removal of cutaneous vascular lesions. Refer to the LCDs for Removal of Benign Skin Lesions, Removal of Benign or Premalignant Lesions, Removal of Skin
Lesions, and Skin Lesion (Non-Melanoma) Removal.

3. **MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):**
   Minnesota DHS does not have a policy statement regarding the use of PDL therapy for treatment of PWS or hemangiomas in its Provider Manual or other specific provider references.

4. **MANDATED BENEFITS UNDER MINNESOTA LAW:**
   

   Current health insurance benefit mandates in Minnesota law, which apply to private, fully-insured group and nongroup policies, requires benefits for port-wine stain elimination.

   Subdivision 1. Scope of coverage. This section applies to all health plans as defined in section 62A.011 that provide coverage to a Minnesota resident.

   Subdivision 2. Required coverage. Every health plan included in subdivision 1 must cover elimination or maximum feasible treatment of port-wine stains for any covered person who is a Minnesota resident. No health carrier may reduce or eliminate coverage due to this requirement.

   Subdivision 3. Rate increases prohibited. The commissioner of commerce shall not approve any rate increases due to coverage required under subdivision 2. No health maintenance organization, as defined in chapter 62D, shall increase rates due to coverage required under subdivision 2.

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**CLINICAL EVIDENCE:**

**SUMMARY:**

There is sufficient evidence of efficacy to support the use of PDL therapy for treatment of superficial hemangiomas or the superficial component of mixed hemangiomas, and for post-involutional hemangiomas and telangiectasia in infants or children requiring definitive treatment to alleviate or prevent medical or psychological complications.

The results from several comparative studies showed that repeated sessions of 585-nanometer (nm) cryogen spray cooled pulsed dye laser (CPDL) therapy at 6- to 8-week intervals is a relatively safe and efficacious treatment for port-wine stain (PWS) lesions, compared with the earlier laser dye technologies, i.e., copper vapor laser or the argon-pumped continuous-wave dye laser, with many patients achieving satisfactory, if not complete, lesion clearing. However, CPDL may be less well tolerated than the 532-nm neodymium:yttrium-aluminum-garnet (Nd:YAG) laser, with similar efficacy. The efficacy of long-pulse pulsed dye laser (PDL) and the long-pulse alexandrite laser was also comparable, as was that of CPDL and indocyanine green-augmented diode laser (ICG-DL). There is also evidence that PDL can be an effective treatment for infants and children with high-risk superficial hemangiomas or mixed hemangiomas with a superficial component that are in the early, proliferative, or involutional phases. Findings from a randomized controlled trial indicate that long-pulse CPDL did not differ from traditional short-pulse PDL in degree of clearance, but did reduce the mean time period of maximum hemangioma proliferation. However, the results of another randomized controlled trial suggest that many hemangiomas may resolve spontaneously over time, and, therefore, the overall health benefit of PDL therapy for hemangiomas...
remains to be demonstrated in patients with no immediate medical or psychological complications resulting from the presence of the lesion. Since more than one treatment session is generally required for a response, PDL therapy may not be advisable for hemangiomas that require immediate attention, including hemangiomas that demonstrate extremely rapid progression, bleeding, or imminent functional impairment. PDL therapy is not efficacious for deep hemangiomas or for the deep component of mixed hemangiomas.

### APPLICABLE CODES:

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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REFERENCES:


43. Greve B, Raulin C. Prospective study of port-wine stain treatment with dye laser: comparison of two wavelengths (585 nm vs. 595 nm) and two pulse durations (0.5 milliseconds vs. 20 milliseconds). Lasers Surg Med. 2004;34(2):168-173.
Scheepers JH, Quaba AA. Does the pulsed tunable dye laser have a role in the management of infantile alexandrite, Er:YAG and CO

Raulin C, Greve B. Retrospective clinical comparison of hemangioma treatment by flashlamp

Liu A, Moy RL, Ross EV, Hamzavi I, Ozog DM. Pulsed dye laser and pulsed dye laser extended pulse pulsed alexandrite


Scheepers JH, Quaba AA. Does the pulsed tunable dye laser have a role in the management of infantile hemangiomas? Arch Dermatol. 2007;143(6):628-632.


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