Prior Authorization Review
Panel MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

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Type of Submission – Check all that apply:
- [ ] New Policy
- [x] Revised Policy*
- [ ] Annual Review – No Revisions

*All revisions to the policy must be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below:

CPB 427 Carbon Dioxide Laser for Actinic Lesions and Other Selected Indications

Clinical content was last revised on 04/26/2018. Additional non-clinical updates were made by Corporate since the last PARP submission, as documented below.

Revision and Update History since last PARP submission:
03/16/2018 - This CPB has been updated with additional coding.
04/26/2018 - This CPB has been revised to state that the following are considered experimental and investigational: (i) carbon dioxide laser surgery for cutaneous angiookeratomas, cutaneous leishmaniasis, elephantiasis nostras verrucosa, female sexual dysfunction, and oral potentially malignant disorders, and (ii) fractional carbon dioxide laser for keloids, and vulvovaginal atrophy symptoms and vaginal rejuvenation in peri-menopausal women.
04/25/2019 – Tentative next scheduled review date by Corporate

Name of Authorized Individual (Please type or print): Dr. Bernard Lewin, M.D.

Signature of Authorized Individual: [Signature]

www.aetnabetterhealth.com/pennsylvania Revised 03/16/2018
Carbon Dioxide Laser for Actinic Lesions and Other Selected Indications

Number: 0427

Policy

Aetna considers carbon dioxide laser treatments medically necessary for the following indications:

- Condyloma
- Individuals with melanoma who have in-transit metastases and palliative surgery is not feasible
- Primary penile tumor (clinical stage Tis, Ta, and T1 Grade 1 to 2)
- Refractory plantar warts (verruca plantaris)
- Removal of actinic keratoses for members who meet applicable criteria set forth in CPB 0567 - Actinic Keratoses Treatments (../500_599/0567.html)
- Removal of superficial basal cell carcinomas of the skin
Aetna considers carbon dioxide laser treatments of other actinic lesions as cosmetic. **Note:** Most Aetna benefit plans exclude coverage of cosmetic procedures.

Aetna considers carbon dioxide laser surgery experimental and investigational for the following indications (not an all-inclusive list) because its effectiveness for these indications has not been established:

- Cutaneous angiokeratomas
- Cutaneous leishmaniasis
- Elephantiasis nostras verrucosa
- Female sexual dysfunction
- Hailey-Hailey disease
- Hidradenitis suppurativa (including scarring)
- Onychomycosis
- Oral potentially malignant disorders
- Peri-implantitis
- Port wine stains
- Vaginal atrophy and dyspareunia (MonaLisa Touch Laser (fractional CO2 laser))

Aetna considers fractional carbon dioxide laser for burn scars, keloids, morphea (localized scleroderma), and vulvovaginal atrophy symptoms and vaginal rejuvenation in perimenopausal women experimental and investigational because its effectiveness for these indications has not been established.

**Background**

The CO$_2$ laser is effective in removing actinic keratoses and superficial basal cell carcinomas of the skin. Use of the CO$_2$ laser to treat non-precancerous actinic lesions, such as skin
wrinkling, is considered cosmetic, and thus subject to the standard contractual exclusion of coverage for cosmetic procedures.

A recent review on laser and photodynamic therapy for the treatment of non-melanoma skin cancer (Marmur et al, 2004) stated that at this time, because the reported recurrence rates are significantly higher than those achieved with standard therapies, laser and photodynamic therapy should be reserved for only those patients who can not undergo surgical therapy for basal cell carcinoma and squamous cell carcinoma.

Iyer et al (2004) evaluated the effectiveness of full face laser resurfacing (UPCO₂ and/or Er:Yag laser) in reducing the number of facial actinic keratoses by comparing pre-operative and post-operative numbers of lesions present and to observe the incidence of non-melanoma skin cancer after full face laser resurfacing (n = 24). These investigators concluded that full face laser resurfacing provides long-term effective prophylaxis against actinic keratoses and may reduce the incidence of actinic keratoses-related squamous cell carcinoma. The findings of this study need to be validated by well-designed trials with long-term follow-up.

Krakowski et al (2014) noted that hidradenitis suppurativa (HS) is a chronic, relapsing, inflammatory skin condition that can have a significant psychosocial impact, both with the active disease and with residual scarring. Although a wide variety of treatment options exist for HS, to the authors' knowledge there are no reported modalities aimed specifically at
treated HS scarring. These researchers described the case of an adolescent female who received medical management of intra-mammary HS followed by successful treatment with fractionated 10,600-nm CO2 laser for her residual cribriform scarring. The authors believed there is great potential for the use of fractionated CO2 laser to improve short- and long-term psychosocial outcomes of HS, promote physical scar remodeling, and possibly alter the disease process itself.

In a systematic review, Ledon et al (2014) stated that onychomycosis is a prevalent and extremely difficult condition to treat. In older and diabetic populations, severe onychomycosis may possibly serve as a nidus for infection, and other more serious complications may ensue. Many treatment modalities for the treatment of onychomycosis have been studied, including topical lacquers and ointments, oral anti-fungals, surgical and chemical nail avulsion, and lasers. Due to their minimally invasive nature and potential to restore clear nail growth with relatively few sessions, lasers have become a popular option in the treatment of onychomycosis for both physicians and patients. Laser or light systems that have been investigated for this indication include the CO2, neodymium-doped yttrium aluminum garnet, 870/930-nm combination, and femtosecond infrared 800-nm lasers, in addition to photodynamic and ultraviolet light therapy.

Furthermore, an UpToDate review on “Onychomycosis” (Goldstein, 2014) states that “Although neodymium-doped:yttrium aluminum garnet (Nd:YAG) and diode lasers have emerged
as treatment options for onychomycosis, data on the efficacy of these interventions are limited and the mechanisms of action and optimal regimens for these treatments remain unclear. Until more robust data supporting the efficacy of laser therapy for onychomycosis is available, we cannot recommend the routine use of this modality”.

In a Cochrane review, Kaushik et al (2014) evaluated the safety and effectiveness of surgical interventions in women with high-grade vulval intraepithelial neoplasia (VIN). These investigators searched the Cochrane Gynaecological Cancer Group Trials Register and the Cochrane Central Register of Controlled Trials (CENTRAL) Issue 11, 2013 and MEDLINE and EMBASE up to December 2013. They also searched registers of clinical trials, abstracts of scientific meetings and reference lists of included studies, and contacted experts in the field. Randomized controlled trials (RCTs) that compared surgical interventions in adult women diagnosed with high-grade VIN were selected for analysis. Two review authors independently abstracted data and assessed risk of bias. They identified 1 RCT (n = 30) that met the inclusion criteria; this trial reported data on CO2 laser surgery versus cavitational ultrasonic surgical aspiration (CUSA). There were no statistically significant differences in the risks of disease recurrence after 1 year of follow-up, pain, scarring, dysuria or burning, adhesions, infection, abnormal discharge or eschar between women who underwent CO2 laser surgery and those who received CUSA. The trial lacked statistical power due to the small number of women in each group and the low number of
observed events, but was at low risk of bias. The authors concluded that the included trial lacked statistical power due to the small number of women in each group and the low number of observed events. The absence of reliable evidence regarding the safety and effectiveness of the 2 surgical techniques (CO2 laser surgery and CUSA) for the management of VIN therefore precluded any definitive guidance or recommendations for clinical practice.

Carbon Dioxide Laser for Hailey-Hailey Disease:

Falto-Aizpurua et al (2015) stated that benign familial chronic pemphigus, or Hailey-Hailey disease (HHD), is a recurrent bullous dermatitis that tends to have a chronic course with frequent relapses. Long-term treatment options include surgery with skin grafting or dermabrasion. Both are highly invasive and carry significant risks and complications. More recently, “laser-abrasion” has been described as a less invasive option with a better side-effect profile. These investigators systematically reviewed the safety and effectiveness of carbon dioxide laser therapy as a long-term treatment option for HHD, and provided a review of other lasers that have been reported with this goal. A total of 23 patients who had been treated with a carbon dioxide laser were identified. After treatment, 10 patients (43%) had had no recurrence, 10 (43%) had greater than 50% improvement, 2 (8%) had less than 50% improvement and 1 (4%) patient had no improvement at all (follow-up period ranged from 4 to 144 months). Laser parameter variability was wide and adverse effects were minimal, including dyspigmentation and
scarring. The authors concluded that reviewed evidence indicated this therapy offers a safe, effective treatment alternative for HHD with minimal risk of side-effects. Moreover, they stated that larger, well-designed studies are needed to determine the optimal treatment parameters.

Also, an eMedicine review on “Familial Benign Pemphigus (Hailey-Hailey Disease) Treatment & Management” (Helm, 2014) noted that “A single case report of remission induced by multiple treatments of long-pulsed alexandrite laser brings additional promise of potential long-term control, though many more studies are needed”. The review did not mention carbon dioxide laser as a therapeutic option.

Furthermore, an UpToDate review on “Hailey-Hailey disease (benign familial pemphigus)” (Morrell, 2015) states that “Surgical and destructive methods have been used in patients with recalcitrant HHD and include carbon dioxide laser or 595 nm pulsed dye laser ablation .... Long healing time, pain, scarring, and uncertain long-term benefit are drawbacks of surgical or destructive therapies for HHD”.

Falto-Aizpurua and colleagues (2015) noted that benign familial chronic pemphigus, or HHD, is a recurrent bullous dermatitis that tends to have a chronic course with frequent relapses. Long-term treatment options include surgery with skin grafting or dermabrasion. Both are highly invasive and carry significant risks and complications. More recently, 'laser-abrasion' has been described as a less invasive option with a better side-effect profile. These investigators

http://qawww.aetna.com/cpb/medical/data/400_499/0427_draft.html 07/15/2018
systematically reviewed the safety and effectiveness of CO2 laser therapy as a long-term treatment option for HHD, as well as provided a review of other lasers that have been reported with this goal. A total of 23 patients who had been treated with a CO2 laser were identified. After treatment, 10 patients (43 %) had had no recurrence, 10 (43 %) had greater than 50 % improvement, 2 (8 %) had less than 50 % improvement and 1 (4 %) patient had no improvement at all (follow-up period ranged from 4 to 144 months). Laser parameter variability was wide and adverse effects were minimal, including dyspigmentation and scarring. The authors concluded that reviewed evidence indicated this therapy offers a safe, effective treatment alternative for HHD with minimal risk of side-effects. Moreover, they stated that larger, well-designed studies are necessary to determine the optimal treatment parameters.

**Melanoma:**

National Collaborating Centre for Cancer’s clinical practice guideline on “Melanoma: Assessment and management” (2015) states that if palliative surgery is not feasible for people with in-transit metastases, CO2 laser is a management option.

**Peri-Implantitis:**

yttrium-aluminum-garnet [Er:YAG]) in the treatment of peri-implantitis and their use in surgical and non-surgical procedures. Human studies for the treatment of peri-implantitis with laser therapy, published between 2002 and January 2014, were collected utilizing the electronic databases PubMed, Ovid, MEDLINE, Cochrane, and Google Scholar. Two reviewers conducted the study selection, data collection, and validity assessment. A total of 812 studies were selected in the initial title search; 13 studies were then chosen for this review. No human studies evaluated the effect of the Nd:YAG laser on peri-implantitis. The CO2 laser was reported to be safe and able to enhance bone regeneration. The diode laser (980 nm) appeared to be effective in its bactericidal effect without changing the implant surface pattern. The Er,Cr:YSGG laser was reported to obtain bone regeneration around a failing implant in 1 case, while the Er:YAG laser exhibited a strong bactericidal effect against periodontopathic bacteria at a low energy level. The authors concluded that although lasers have shown promising results in reducing clinical signs of peri-implantitis, because of the limited sample sizes and short follow-up periods, no firm conclusion can be drawn at this moment. They stated that there is a need for more well-designed, longitudinal, RCTs.

**Port Wine Stains:**

Lanigan and Cotterill (1990) noted that the CO2 laser was used to treat 51 patients with port-wine stain (PWS); 29 patients were adults who had failed to respond to argon or continuous wave dye laser therapy and 22 patients were
children with pink PWS. Follow-up assessment of 40 patients 12 months after treatment revealed an excellent or good result in 74% of adults and 53% of children. The authors concluded that the results observed in adult “therapeutic failures” was encouraging and CO2 laser therapy can be advised for this group. Two children had a poor result, 1 with a hypertrophic scar, and treatment in this age group with the CO2 laser should be considered with caution.

In a Cochrane review, Faurschou et al (2011) studied participant satisfaction, clinical efficacy, and adverse effects of the treatment of PWSs by lasers and light sources. These investigators searched the following databases up to April 2010: the Cochrane Skin Group Specialised Register, the Cochrane Central Register of Controlled Trials (Clinical Trials) in The Cochrane Library, MEDLINE (from 2005), EMBASE (from 2007), LILACS (Latin American and Caribbean Health Science Information database, from 1982), and reference lists of articles. They also searched online trials registries for ongoing trials and contacted trial authors where appropriate. Randomized clinical trials (RCTs) of lasers or light sources for the treatment of PWSs were selected for analysis. The outcomes of interest were participant satisfaction, reduction in redness of the PWS as determined by clinical evaluation, and short- and long-term adverse effects of the treatments; 3 authors independently extracted data and assessed trial quality. These researchers included 5 RCTs involving a total of 103 participants; all of the trials used a within-participant design. The interventions and outcomes were too varied to be combined statistically. All trials used the pulsed dye laser
for comparisons. None of the studies focused on participant satisfaction, which was one of the primary outcomes, but participant preference was evaluated in 3 of 5 studies. Participants preferred the pulsed dye laser to intense pulsed light based on the clinical effect. They marginally preferred the Neodymium:YAG (yttrium-aluminum-garnet) (Nd:YAG) laser to the pulsed dye laser due to shorter lasting purpura, and pulsed dye laser in conjunction with cooling was preferred to treatment with pulsed dye laser alone. All trials examined short-term efficacy of less than 6 months after treatments with the pulsed dye laser, intense pulsed light, and Nd:YAG laser. The pulsed dye laser was evaluated in all 5 trials. Depending upon the setting of the pulsed dye laser, this resulted in more than 25% reduction in redness. This was after 1 to 3 treatments for up to 4 to 6 months post-operatively in 50% to 100% of the participants. There was only 1 study each of intense pulsed light and Nd:YAG laser. Two trials had no occurrence of long-term adverse effects, i.e. 6 months after treatment. Three trials reported pigmentary alterations in 3% to 24% of the participants, with the highest percentage occurring in Chinese participants with darker skin types. In 1 study, 1 participant experienced scarring of the skin caused by a too-high dose of the laser used. Short-term side-effects included pain, crusting, and blistering in the first 2 weeks after treatment. The authors concluded that the pulsed dye laser led to clinically relevant clearance of port-wine stains. A limited number of RCTs evaluated the efficacy from intense pulsed light and other laser types. They stated
that high-quality RCTs are needed to assess individual efficacy from different lasers and light sources, as well as participant satisfaction.

In an eMedicine review on “Capillary Malformation Treatment & Management”, Antaya (2014) stated that “Flashlamp-pumped pulsed-dye laser (PDL) surgery is the treatment of choice for capillary malformations .... Earlier laser therapies that caused an unacceptably high rate of scarring are not recommended; these therapies include carbon dioxide laser, copper vapor laser, and argon laser”.

Furthermore, an UpToDate review on “Capillary malformations (port wine stains): Clinical features, diagnosis, and associated syndromes” (Galbraith, 2016) states that “Pulsed dye laser (PDL) therapy is considered the standard of care for the treatment of capillary malformations. It is based on the concept of selective photothermolysis with oxyhemoglobin as the target. PDL treatment irreversibly damages the capillary vessel wall with minimal damage to the overlying epidermis, which leads to lightening of the port wine stain without scarring”. It does not mention CO2 laser as a therapeutic option.

Primary Penile Tumors:

Maranda and colleagues (2016) stated that erythroplasia of Queyrat (EOQ) is a squamous cell carcinoma in-situ most commonly located on the glans penis or prepuce. Erythroplasia of Queyrat accounts for approximately 10 % of all penile malignancies and may lead to invasive squamous cell carcinoma. Standard therapy
includes local excision, partial or total penectomy, cryotherapy, and topical cytotoxic agents. Treatment of EOQ has proven to be challenging due to low response rates and recurrence. In addition, radical procedures can significantly affect sexual function and quality of life (QOL). Alternative laser treatments and PDT offer promising results for treating EOQ. These investigators performed a systemic review of the literature for articles discussing laser and light therapy for EOQ. Among the patients treated with the CO2 laser, 81.4% of cases had complete remission after 1 session of treatment. Patients treated with PDT presented with more variable results, where 62.5% of those treated with MAL-PDT achieved complete remission; ALA-PDT treatment showed a similar rate of remission at 58.3%. One study utilized the Nd:YAG laser, which resulted in a recurrence of the lesion in 4 of the 5 patients treated. Of the methods reviewed, the CO2 laser offered the most promising results with a cosmetically excellent prognosis. The authors concluded that further studies with larger power and longer follow-up times are needed to determine the optimal treatment regimen for this penile malignancy.

Zreik and associates (2017) evaluated the outcome of CO2 laser treatment of penile intraepithelial neoplasia (PeIN). These researchers performed a retrospective review of 47 patients who underwent CO2 laser ablation of PeIN, from May 2008 to June 2015. All patients underwent acetic acid mapping and had their lesions ablated with a Lumenis Shaplan CO2 laser device. Patients had regular follow-up and further suspicious areas underwent re-biopsy. After laser treatment, 8 men (17%) had a
recurrence and the average time to recurrence was 19.4 months; 7 of the 8 patients with recurrences, pathologically had further PeIN and 1 patient developed G1 pT1 disease. These patients underwent further laser treatment, glans resurfacing or local excision. No patients required penectomy. The average length of follow-up was 29 months (range of 1 to 76). Penile cancer-specific survival was 100 % and overall survival (OS0 was 98 %. No patients required re-admission or developed other long-term complications, such as meatal stenosis from their treatment. The authors concluded that CO2 laser treatment for PeIN is effective due to its 100 % response rate, low progression rate and lower recurrence rate compared with topical agents. The laser has minimal morbidity with cosmetically acceptable outcomes compared to more invasive resurfacing surgeries.

Furthermore, National Comprehensive Cancer Network's clinical practice guideline on “Penile cancer” (Version 1.2017) recommends the use of therapeutic laser (CO2, Nd:YAG, and KTP) to treat selected (clinical stage Tis, Ta, and T1 Grade 1 to 2) primary penile tumor (category 2B recommendation).

Cutaneous Angiokeratomas:

Nguyen and colleagues (2017) noted that angiokeratomas can present therapeutic challenges, especially in cases of extensive lesions, where traditional surgical methods carry high risks of scarring and hemorrhage. Argon, pulsed dye (PDL), neodymium-doped yttrium aluminum garnet (Nd:YAG), copper vapor,
potassium titanyl phosphate, CO2, and erbium-doped yttrium aluminum garnet (Er:YAG) lasers have emerged as alternative options. These researchers reviewed the use and efficacy of lasers in treating angiokeratomas. A PubMed search identified randomized clinical trials, cohort studies, case series, and case reports involving laser treatment of cutaneous angiokeratomas. A total of 25 studies were included. Quality ratings were assigned using the Oxford Centre for Evidence-Based Medicine scheme. Several laser modalities were effective in treating multiple variants of angiokeratomas. Vascular lasers like PDL, Nd:YAG, and argon were the most studied and of these, PDL offered the safest side effect profile. Nd:YAG may be more effective for hyperkeratotic angiokeratomas. Combination treatment with multiple laser modalities had also demonstrated some success. The authors concluded that lasers are a promising therapeutic option for angiokeratomas, but current use is limited by the lack of treatment guidelines. They stated that there are limited high quality studies comparing laser treatments to each other and to non-laser options; additional studies are needed to establish guidelines and to optimize laser parameters.

Cutaneous Leishmaniasis:

Palumbo (2009) stated that cutaneous leishmaniasis is the most common form of leishmaniasis. It is a skin infection caused by a single-celled parasite that is transmitted by sand fly bites. There are about 20 species of Leishmania that may cause cutaneous leishmaniasis. Some Leishmania species are
closely linked to humans and are therefore found in cities (Leishmania tropica), whereas some are more traditionally associated with animal species and are therefore considered zoonoses (Leishmania major). The evidence for optimal treatment of cutaneous leishmaniasis is patchy. Although the cutaneous form of the disease is often self-limiting, it does result in significant scarring and can spread to more invasive, mucocutaneous disease. Therefore, treatment may be considered to prevent these complications. The author discussed drugs for systemic and topical treatment with regard to their application, use, and adverse effects.

A Cochrane review on “Interventions for Old World cutaneous leishmaniasis” (Heras-Mosteiro et al, 2017) does not mention CO2 laser as a therapeutic option. Furthermore, an UpToDate review on “Cutaneous leishmaniasis: Treatment” (Aronson, 2018) does not mention CO2 laser as a therapeutic option.

Elephantiasis Nostras Verrucosa:

Robinson and colleagues (2018) stated that elephantiasis nostras verrucosa (ENV) is a disfiguring skin condition that is difficult to treat. Existing treatment modalities serve to improve cosmesis or treat symptoms. These investigators reported a case of ENV with lymphocutaneous fistula successfully treated with ablative CO2 laser. A 57-year old woman with biopsy-proven ENV with lymphocutaneous fistula was treated with ablative CO2 laser to the symptomatic area of her right thigh in 3 treatment sessions over 6 months. The patient had resolution of lymphocutaneous drainage as
well as 90% improvement in the appearance of ENV lesions at the 1-month follow-up visit. The authors concluded that ablative CO2 laser may provide cosmetic, symptomatic, and medical benefit for patients with localized ENV. These preliminary findings need to be validated by well-designed studies.

Female Sexual Dysfunction:

Weinberger and associates (2018) stated that female sexual dysfunction (FSD) is a highly prevalent condition. Nevertheless, the scientific literature has only recently begun to accumulate evidence for treatment modalities that address the underlying etiologies of FSD. In a systematic review, these investigators elucidated what treatments are effective across the various symptom complexes of FSD. Utilizing meta-analysis of observational studies in epidemiology guidelines, these researchers conducted a systematic review of PubMed, Embase, clinicaltrials.gov, and the Cochrane Review databases. A total of 11 search strings, encompassing the terms "female sexual dysfunction" and "treatment", in combination with "vulvovaginal atrophy", "vaginismus", "vaginal atrophy", "vulvodynia", "vestibulitis", "hypoactive sexual desire", "arousal disorder", "sexual pain disorder", "genitourinary syndrome of menopause" and "orgasmic disorder" were utilized. A total of 605 relevant articles were retrieved; and 103 original studies met inclusion criteria. A total of 42 treatment modalities were utilized, including 26 different classes of medications. Although outcome measures varied, the most substantial improvement across multiple studies was noted with various
hormonal regimens. The most common treatments included hormonal therapy (25 studies), phosphodiesterase type-5 inhibitors (9 studies), botulinum toxin A (5 studies), and flibanserin (5 studies). The psychotherapeutic approach was detailed in 36 articles while 3 studies utilized homeopathic treatments. Numerous treatments showed efficacy in a single-case series, including the promising results associated with the micro-ablative CO2 laser. Despite the marked improvement in specific FSD domains, neither pharmacologic treatments nor psychotherapeutic interventions demonstrated consistent disease resolution. The authors concluded that treatment of FSD is multi-factorial; medications alone did not resolve FSD. The wide variability of treatment and outcome measures across the literature attested to the complexity of FSD and the need for a treatment algorithm that addresses all 4 domains of FSD.

Hidradenitis Suppurativa:

Saunte and Jemec (2017) reviewed the diagnosis, epidemiology, and treatment of hidradenitis suppurativa (HS) with an emphasis on advances in the last 5 years. A literature search was conducted using PubMed, Medline (Medical Subject Headings [MeSH]), and Embase to include recently published treatment studies (searched from September 1, 2011, to May 1, 2017). Reviews, guidelines, conference abstracts, and studies with less than 10 patients were excluded. Furthermore, internet searches for guidelines on HS using Baidu, Bing, Google, and Qwant browsers were performed. The diagnosis of HS is made by lesion morphology (nodules,
Abscesses, tunnels, and scars), location (axillae, inframammary folds, groin, peri-genital, or perineal), and lesion progression (2 recurrences within 6 months or chronic or persistent lesions for greater than or equal to 3 months).

Hidradenitis suppurativa is more common than was previously thought based on epidemiological analysis (0.05 % to 4.10 %). Disability from HS can be significant. Patients with HS may have significant co-morbidities (e.g., obesity, metabolic syndrome, diabetes, and arthritis) and increased all-cause mortality (incidence rate ratio, 1.35 [95 % confidence interval [CI]: 1.15 to 1.59]). Antibiotic treatment with combinations of clindamycin and rifampicin, or ertapenem followed by combination rifampicin, moxifloxacin, and metronidazole for 6 months is effective. Adalimumab is effective in a significant proportion of patients and treatment with interleukin-1 (IL-1) and IL-12 receptor subunit beta 1 (Rb1) antibodies may also be useful. Tissue-sparing surgical techniques and CO2 laser treatments also are available, but the evidence on clinical outcomes with these approaches is limited.

Oral Potentially Malignant Disorders:

Cloitre and colleagues (2018) noted that oral cancer is a public health issue worldwide. Oral potentially malignant disorders (OMPDs) are lesions of the oral mucosa that are predisposed to malignant transformation. The mainstay of OMPDs treatment around the world is now the CO2 laser but the reported recurrence and malignant transformation rates vary widely in the literature. These researchers estimated the recurrence and the malignant transformation
rates of OPMDs treated with CO2 laser at the University Hospital of Bordeaux, in France, from 2010 to 2014, and identified associated factors with recurrence or malignant transformation. They conducted a retrospective study in patients with a minimum follow-up of 12 months. Collected variables included characteristics of the patients (gender, age, alcohol and tobacco consumption, previous diagnosis of graft-versus-host disease [GVHD], previous treatments for OPMD or for upper aero-digestive tract cancers and human immunodeficiency virus [HIV] infection), characteristics of the lesions (form, color, size, location, degree of dysplasia), laser treatment outcome (complications, recurrence, malignant transformation). A total of 25 patients were included; mean follow-up was 28.9 months. Recurrence was observed in 11 patients (44%). Annual recurrence rate was 18.3% and annual malignant transformation rate was 1.7%. Hyperplasia without dysplasia was the only factor found to be statistically associated with recurrence. The authors concluded that these findings suggested that OPMDs treated by CO2 laser vaporization had high recurrence rates, particularly those presenting hyperplasia. They stated that a standardized definition of recurrence would be necessary for inter-study comparisons; long-term follow-up is recommended in order to detect and treat squamous cell carcinoma in its early stages. Moreover, these investigators stated that RCTs should be used to evaluate the outcome of different treatment methods and multi-center studies could increase the power of statistical analyses.

The authors stated that this study had several
drawbacks. First, this was a retrospective study. It was based on complete records from the archives of the University Hospital of Bordeaux. Second, the sample size was small (n = 25) but similar to that reported in some studies with CO2 laser vaporization. This was due to the characteristics of the studied lesions themselves which were rare (less than 5%) and required further follow-up to observe a potential recurrence or malignant transformation. These researchers had a small sample size despite a 4-year screening period, providing a small power to identify associated factors, but on the other hand, they had data of good quality from a homogeneous sample (severe dysplasia excluded, all treated by CO2 laser by the same surgeon) followed-up at least 12 months as indicated by Brouns et al. These lesions should become even rarer as the prevalence of tobacco smoking is declining worldwide, pointing out the need for future systematic reviews and meta-analyses, in which this study can contribute, and collaborative multi-center studies.

Vaginal Atrophy and Dyspareunuria (MonaLisa Touch Laser):

Tschanz et al (2001) observed 3 cases of vulvodynia after CO2 laser (pulse or scan) treatment of condylomata acuminata (n = 1) or Bowenoid papulosis (n = 2) of the female genital mucosa. Laser treatment was associated with a considerable delay in healing (3 to 4 months) and chronic pain. The histology of the treated areas showed a scar tissue and severe mucosal atrophy. The occurrence of painful scars
following CO2 laser treatment could be related to an inadequate laser technique considering the morphology of the vagina.

In a pilot study, Salvatore et al (2014) evaluated the feasibility and effectiveness of fractional CO2 laser in the treatment of vulvo-vaginal atrophy (VVA) in post-menopausal women. VVA symptoms were assessed before and after 3 applications of laser over 12 weeks in 50 women (aged 59.6 ± 5.8 years) dissatisfied with previous local estrogen therapies. Subjective (visual analog scale) and objective (Vaginal Health Index Score, VHIS) measures were used during the study period to assess VVA. Quality of life was measured by using the SF-12. A subjective scale to evaluate the degree of pain related to the laser application and the degree of difficulty to perform the laser procedure was used. Fractional CO2 laser treatment was effective to improve VVA symptoms (vaginal dryness, vaginal burning, vaginal itching, dyspareunia, dysuria; p < 0.001) at 12-week follow-up, as well as the VHIS (13.1 ± 2.5 at baseline versus 23.1 ± 1.9; p < 0.001). Both physical and mental scores of quality of life were significantly improved in comparison with baseline (p < 0.001). Satisfaction with the laser procedure was reported by 42 women (84 %) and a minimal discomfort was experienced at the 1st laser application, mainly because of the insertion and the movements of the probe. Finally, the technique was very easy to perform in all women starting from the 2nd application at week 4 and no adverse events were recorded during the study period. The authors concluded that a 12-week treatment with the fractional CO2 laser was feasible and induced a significant
improvement of VVA symptoms by ameliorating vaginal health in postmenopausal women. They stated that further controlled studies should be performed to confirm the present data and to assess the long-term effects of the laser procedure on vaginal tissues.

In a prospective study, Salvatore et al (2015) examined the effects of fractional micro-ablative CO2 laser on sexual function and overall satisfaction with sexual life in post-menopausal women with VVA. A total of 77 post-menopausal women (mean age of 60.6 ± 6.2 years) were treated for VVA symptoms with the fractional micro-ablative CO2 laser system (SmartXide(2) V (2)LR, MonaLisa Touch, DEKA, Florence, Italy). Sexual function and quality of life were evaluated with the Female Sexual Function Index (FSFI) and the Short Form 12 (SF-12), respectively, both at baseline and at 12-week follow-up. A 10-mm visual analog scale was used to measure the overall satisfaction with sexual life and the intensity of VVA symptoms (vaginal burning, vaginal itching, vaginal dryness, dyspareunia and dysuria) before and after the study period. These researchers observed a significant improvement in the total score and the scores in each specific domain of the FSFI at 12-week follow-up compared to baseline (p < 0.001). After concluding the laser treatment, the overall satisfaction with sexual life significantly improved (p < 0.001). Seventeen (85 %) out of 20 (26 %) women, not sexually active because of VVA severity at baseline, regained a normal sexual life at the 12-week follow-up. Finally, these investigators also found a significant improvement in each VVA symptom (p < 0.001) and in quality-of-life evaluation, both for the
scores in the physical (p = 0.013) and mental (p = 0.002) domains. The authors concluded that fractional micro-ablative CO2 laser treatment is associated with a significant improvement of sexual function and satisfaction with sexual life in post-menopausal women with VVA symptoms.

There is currently insufficient evidence to support the use of MonaLisa Touch Laser (fractional CO2 laser) for gynecologic health (e.g., vaginal atrophy and dyspareunia).

Arunkalaivanan and colleagues (2017) noted that interest in laser therapy as a non-hormonal option for the treatment of genitourinary syndrome of menopause (GSM) has increased. These investigators conducted a systematic review of the use of laser therapy for the relief of GSM symptoms. A total of 6 electronic databases were searched and conference abstracts were searched manually from the introduction of laser therapy to the present date. The keywords used were: "genitourinary syndrome", "vulvovaginal atrophy", "postmenopausal symptoms", "laser therapy" and "fractional laser treatment". Of the 165 articles identified in the search, none was a RCT. As a result, these researchers included 3 observational studies without a control group and 1 case-control study that met the inclusion criteria. The total number of women included in the 4 studies was 220. The collated data suggested that laser therapy may be valuable as a non-hormonal therapeutic modality in the management of GSM. Moreover, they stated that higher quality of evidence from RCTs is needed to establish the efficacy of laser
treatment in the management of GSM.

An UpToDate review on “Treatment of genitourinary syndrome of menopause (vulvovaginal atrophy)” (Bachmann and Santen, 2018) states that “Laser treatment is available for potential treatment of vulvovaginal atrophy with/without urinary incontinence. The laser technologies deliver either fractional CO2 laser energy, and some systems use non-ablative photothermal Erbium:YAG-laser to the vaginal wall tissue. Laser therapy typically consists of 3 laser treatment sessions over a specified time period (usually 1 session every 4 to 6 weeks) ... Laser devices have not been approved by the US Food and Administration for the treatment of vulvovaginal atrophy. The American College of Obstetricians and Gynecologists has advised that: Although initial observational data indicate potential utility, additional data from randomized trials are needed to further assess the efficacy and safety of this procedure in treating vulvovaginal atrophy, particularly for long-term benefit; and obstetrician-gynecologists should be cognizant of the evidence regarding innovative practices and should be wary of adopting new or innovative approaches on the basis of promotions or marketing. Additional large clinical trials are actively recruiting subjects”.

**Fractional CO2 Laser for Burn Scars:**

Connolly and colleagues (2014) stated that fractional CO2 laser has recently emerged as a promising therapeutic modality to improve the texture and appearance of burn scars. An issue in many burn scars is persistent erythema, which
traditionally has been treated with vascular lasers. Interestingly, fractional CO2 lasers have been shown to improve the appearance of burn scars, including erythema, but no mechanism has been proposed for this change. These researchers evaluated the histopathological changes in vasculature in burn scars treated with fractionated CO2 laser, and described the mechanism behind reduced erythema following treatment. This was an uncontrolled, prospective study of 10 patients with mature burn scars, from a clinical and histological perspective. Biopsy specimens were obtained before and 2 months after 3 treatment sessions. Anti-CD31 immuno-staining was performed to highlight vascular patterns in biopsy specimens. In histological analysis, an increase in vascular density, particularly of small caliber vessels, was seen following treatment, with an 82.6% average increase in vasculature (p = 0.028). This increase in vascularity correlated with a decrease in clinical erythema and vascularity scores, measured using the Vancouver Scar Scale. The authors concluded that mature hypertrophic burn scars treated with a fractional CO2 laser showed a statistically significant increase in vascular density in the superficial dermis; but a non-statistical decrease in clinically perceived erythema and improvement of overall appearance was observed.

International guideline recommendations on scar management (Gold et al, 2014) stated that “ablative and non-ablative fractional lasers are focus of much current research and that the evidence is generally favorable in scientific literature for preventative and treatment applications”. Other guidelines on scar
management have reached similar conclusions about the investigational nature of CO2 laser for burn scars (Monstrey et al, 2014).

In a controlled study, El-Zawahry and associates (2015) evaluated and correlated the clinical and histopathological effects of fractional CO2 laser on thermal burns. A total of 15 patients (11 with hypertrophic and 4 with keloidal scars) received 3 CO2 fractional laser sessions every 4 to 6 weeks; 50% of the scar was untreated as a control. Clinical evaluation by Vancouver, PSOAS scores, and photography before, monthly, and 3 months after the last laser session was performed; 10 patients were evaluated histopathologically by standard H&E, Masson trichrome, and Elastica von Gieson special stains. Hypertrophic scars (HTSs) showed textural improvement and a significant decrease of Vancouver, POSAS observer, and patient scores by the end of follow-up period in the laser-treated area (p = 0.011, 0.017 and 0.018, respectively) unlike keloidal scars. Histopathology revealed significant decrease in scar thickness in HTSs only (p < 0.001) as well as a significant decrease in collagen bundle thickness and density in the upper dermis in both types of scars. The authors concluded that fractional CO2 laser is a possible safe and effective modality for the treatment of hypertrophic burn scars with improvement achieved both clinically and histopathologically. These preliminary findings from a small study (n = 15) need to be validated by well-designed studies.
Levi and co-workers (2016) described their results and patient-reported outcomes with the use of fractional CO2 laser for the treatment of burn-related scarring. These researchers performed a retrospective study of all patients who underwent CO2 laser procedures for treatment of symptomatic burn scars and skin grafts. Burn injury and laser treatment demographics, as well as complications, were reported. A questionnaire was administered to all patients and included patient-reported outcome measures aimed at understanding the patient experience and their subjective response to treatment. A total of 387 CO2 laser procedures were performed on 131 patients for the treatment of symptomatic burn scars and skin grafts between October 1, 2011, and May 1, 2014 (average of 2.95 procedures/patient; range of 1 to 11). Average time between injury and first laser was 597.35 days (range of 60 to 13,475). Average time between laser treatments (when multiple) was 117.73 days (range of 22 to 514). There were no infections requiring treatment with oral antibiotics. Overall patient satisfaction with laser therapy was 96.7 %. Patients reported reductions in neuropathic pain, tightness (contracture), and pruritus (54.0, 50.6, and 49.0 %, respectively). The authors concluded that fractional photothermolysis utilizing the CO2 laser is a safe and effective modality for the treatment of symptomatic burn scars, donor sites, and skin grafts. Patient satisfaction with this procedure is high, and complications were low. Significant improvements in scar appearance, pliability, tightness, neuropathic pain, and pruritus were
commonly reported. The major drawbacks were its retrospective design and that it was a single-center study.

Ządkowski and colleagues (2016) noted that treatment of hypertrophic scars arising as a result of thermal burns in children is still a big problem. The results of the treatment are not satisfactory for patients and parents, and new methods of treatment are still being investigated. These researchers presented the use of one of the most modern CO2 lasers (Lumenis Encore laser equipped with a Synergistic Coagulation and Ablation for Advanced Resurfacing module) in the treatment of hypertrophic scars in children after burns. From March to April of 2013, a group of 47 patients aged 6 to 16 years underwent 57 laser surgery treatments. The average time from accident was 7.5 years. The results of treatment were investigated in 114 areas. The assessed areas were divided into 2 groups: (i) 9-cm area 1, where the thickness of the scar measured by physician was the lowest, and (ii) 9-cm area 2, where the thickness of the scar was the biggest. The results were considered on the Vancouver Scar Scale (VSS) independently by the surgeon and by parents 1, 4, and 8 months after the procedure. In addition, ultrasound evaluation of the scar thickness before and after laser procedure was made; VSS total score improved in all areas assessed by both the physician and parents. The biggest change in total VSS score in area 1 in the evaluation of the investigator was obtained at follow-up after the 1st month of treatment (average of 7.23 points before and 5.18 points after the 1st month after surgery -- a difference of 2.05 points). Scar ratings by
parents and the physician did not differ statistically (p < 0.05). In the ultrasound assessment, the improvement was statistically significant, more frequently for both minimum and maximum thickness of the scars (B-mode measures) (p < 0.05). The authors concluded that the use of a CO2 laser in the treatment of hypertrophic scars in children is a safe and effective method.

The main drawback of this study was that these investigators included only the patients with hypertrophic scars, not all the children with burn scars. The authors noted that they knew that the keloids treatment results would be worse, and if they mixed all the scars, result would not be so great. The other drawback was excluding patients with parents who do not pay enough attention to their children: in order to achieve good long-term outcomes, strict control of the healing process after the procedure is necessary. The healing process takes about 10 to 14 days maximum; therefore, the exclusion criteria rule out the patients with poor social and living conditions: parents who do not care about sufficient assessment, parents who did not respond to previous recommendations, missed check-outs, or do not pay enough attention to hygiene process for their children. These investigators stated that laser therapy in the treatment of hypertrophic scars is still at a very early stage of development. There is no guidance on which type of laser or energy dose should be used or the frequency of repeated treatments. This is connected with the high volatility of scars, their different location, and morphology. They stated that it appeared that the further development of technologies will
allow reduction of the number of complications and increase the effectiveness of treatment; the results obtained in this work are very promising but of course need further evaluation.

Furthermore, an UpToDate review on “Management of keloid and hypertrophic scars following burn injuries” (Gauglitz, 2017) states that “Fractional lasers might play a promising role in the treatment of widespread burn scars. Improvements in both clinical and structural features of burn scars have been reported after fractional CO2 laser procedures. However, more in-depth studies are needed to identify the underlying mode of action and clinical treatment regimens before definite recommendations for treatment protocols can be made”.

In an uncontrolled, open-label, clinical trial, El-Hoshy and colleagues (2017) evaluated the efficacy of fractional CO2 laser use in the treatment of mature burn scars. A total of 20 patients with mature burn scars were included in the study. A total of 3 fractional CO2 laser sessions were given, 4 to 8 weeks apart. Primary outcome was measured using 2 scar scales, the Vancouver Scar Scale and the Patient and Observer Scar Assessment Scale. Secondary outcomes included evaluation of collagen and elastic fibers using routine hematoxylin and eosin, Masson’s trichrome, and orcein stains. Outcomes were measured 2 months after the last laser session. Both Vancouver Scar Scale and Patient and Observer Scar Assessment Scale showed significant reduction following treatment (p < 0.001). Scar relief and pliability improved most followed by vascularity. Pigmentation improved the least. Percent improvement in
Patient and Observer Scar Assessment Scale patients' overall assessment was 44.44%. The pattern and arrangement of collagen and elastic fibers showed significant improvement (p < 0.001, p = 0.001, respectively), together with significant improvement in their amounts (p = 0.020, p < 0.001, respectively). No significant correlation existed between clinical and histopathological/histochemical scores. Side effects and complications were mild and tolerable. The authors concluded that fractional CO2 laser can be a safe and effective modality in the treatment of post-burn scars. It achieved significant change in the opinion of the patients about their scar appearance. Moreover, they noted that limitations of this study included its small sample size (n = 20) and the relatively short follow-up period (2 months).

**Fractional CO2 Laser for Morphea/Localized Scleroderma:**

Morphea is a rare fibrosing skin disorder that occurs as a result of abnormal homogenized collagen synthesis. Jacoby (2017) noted that ablative fractional laser therapy has been shown to be effective in a few patients with morphea (localized scleroderma) (citing Kineston, et al., 2011)

Shalaby and colleagues (2016) evaluated the effectiveness of fractional CO2 laser as a new modality for the treatment of localized scleroderma and compared its results with the well-established method of UVA-1 phototherapy. A total of 17 patients with plaque and linear morphea were included in this parallel intra-individual comparative RCT. Each with 2
comparable morphea lesions that were randomly assigned to either 30 sessions of low-dose (30 J/cm²) UVA-1 phototherapy (340 to 400 nm) or 3 sessions of fractional CO₂ laser (10,600 nm-power 25 W). The response to therapy was then evaluated clinically and histopathologically via validated scoring systems. Immunohistochemical analysis of TGF-β1 and MMP1 was done. Patient satisfaction was also assessed. Wilcoxon signed rank test for paired (matched) samples and Spearman rank correlation equation were used as indicated. Comparing the 2 groups, there was an obvious improvement with fractional CO₂ laser that was superior to that of low-dose UVA-1 phototherapy. Statistically, there was a significant difference in the clinical scores (p = 0.001), collagen homogenization scores (p = 0.012), and patient satisfaction scores (p = 0.001). The authors concluded that fractional CO₂ laser is a promising treatment modality for cases of localized morphea.

Fractional CO₂ Laser for Keloids:

Annabathula and co-workers (2017) evaluated the efficacy of fractional CO₂ laser, long pulse Nd:YAG laser and PDL in the management of keloids. A total of 15 patients with keloids were treated by fractional CO₂ laser, followed by PDL and long pulse Nd:YAG laser at monthly intervals; 4 patients discontinued the study and were lost for follow-up. Photographs were taken at the beginning of the treatment and at the end of 5 sessions. Clinical improvement was analyzed based on a visual analog scale (VAS) graded by 3 blinded observers after assessing the clinical photographs for the improvement in
size, color and aesthetic impression. Of the 11 patients, 1 patient had excellent improvement, 1 patient had good improvement, 4 patients had moderate improvement, 2 patients had mild improvement and 3 had no improvement. The authors concluded that lasers may have a synergistic effect when combined with other modalities of treatment; but cannot be used as monotherapy in the treatment of keloids. The drawbacks of this study were its small sample size (n = 15) and the limited number of laser sessions (n = 5).

Fractional CO2 Laser for Vulvovaginal Atrophy Symptoms and Vaginal Rejuvenation in Peri-Menopausal Women:

Arroyo (2017) examined a novel fractional CO2 laser for treatment of symptoms associated with VVA in peri-menopausal women. The study included 21 peri-menopausal women (mean age of 45 ± 7 years) treated 3 times by CO2 laser resurfacing and coagulation of the vaginal canal tissue and mucosal tissue of the introitus. Vaginal health index (VHI) scores were computed by the investigator at baseline and follow-ups. Subjects reported on sexual function, satisfaction, and improvement with treatment. A VAS was used to measure discomfort with treatment. Vaginal health and subject assessment of vaginal symptoms improved with successive treatments. At 12 weeks following the 3rd treatment, 82 % of the patients showed a statistically significant improvement in VHI (p < 0.05). Additionally, 81 % of subjects reported improvement in sexual gratification, 94 % reported improvement in vaginal rejuvenation, and 100 % reported
satisfaction with treatment. VHI improvement remained significant at 6 to 8 months after treatments ($p < 0.01$). Most patients (97%) reported no to mild discomfort with treatment. Responses were mild and transient following treatment, with itching being the most commonly reported (20%) side effect. The authors concluded that fractional CO2 laser treatment was associated with improvement of vaginal health and amelioration of symptoms of VVA, resulting in improved sexual function in peri-menopausal women. Treatment time was quick, and there was minimal discomfort associated with treatment. Moreover, they stated that investigation of clinical outcome in a larger study population is needed; investigation of long-term clinical outcome, up to 12 months post-treatment, in a post-menopausal population is currently ongoing at a multi-center study in the USA.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

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<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>CPT codes covered if selection criteria are met:</td>
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<tr>
<td>17000 - 17004</td>
<td>Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement) premalignant lesions (e.g., actinic keratoses)</td>
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<tr>
<td>17260 - 17286</td>
<td>Destruction, malignant lesion (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement)</td>
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<td>CPT codes not covered for indications listed in the CPB:</td>
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<td>Code</td>
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<td>0479T-0480T</td>
<td>Fractional ablative laser fenestration of burn and traumatic scars for functional improvement</td>
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<td>17110</td>
<td>Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), of benign lesions other than skin tags or cutaneous vascular proliferative lesions; up to 14 lesions [carbon dioxide laser surgery]</td>
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<td>17111</td>
<td>15 or more lesions [carbon dioxide laser surgery]</td>
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ICD-10 codes covered if selection criteria are met:

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<td>C44.01, C44.111 - C44.119, C44.211 - C44.219, C44.310 - C44.319, C44.41, C44.510 - C44.519, C44.611 - C44.619, C44.711 - C44.719, C44.81, C44.91</td>
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<td>C60.0 - C60.9</td>
<td>Malignant neoplasm of penis</td>
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<tr>
<td>L57.0</td>
<td>Actinic keratoses</td>
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ICD-10 codes not covered if selection criteria are met:

http://qawww.aetna.com/cpb/medical/data/400_499/0427_draft.html  07/15/2018
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<td>B35.1</td>
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<td>F52.6</td>
<td>Dyspareunia not due to a substance or known physiological condition</td>
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<td>L56.5</td>
<td>Disseminated superficial actinic porokeratosis (DSAP)</td>
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<td>L73.2</td>
<td>Hidradenitis suppurativa</td>
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<tr>
<td>L90.5</td>
<td>Scar conditions and fibrosis of skin [burn scars]</td>
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<td>L94.0</td>
<td>Localized scleroderma [morpha]</td>
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<td>Post-osseointegration biological failure of dental implant</td>
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<td>N94.10 - N94.19</td>
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<td>Congenital non-neoplastic nevus</td>
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<tr>
<td>Q82.8</td>
<td>Other specified congenital malformations of skin [Hailey-Hailey]</td>
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</table>

The above policy is based on the following references:


47. Nguyen J, Chapman LW, Korta DZ, Zachary CB. Laser treatment of cutaneous


**Carbon Dioxide Laser for Hailey-Hailey Disease:**

1. Helm TN. Familial benign pemphigus (Hailey-Hailey disease) treatment & management.
Fractional CO2 Laser:


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number:
0427 Carbon Dioxide Laser for Actinic Lesions and Other Selected Indications

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania

revised 03/16/2018