Select Health

Select Health Medical Policies

Dermatology Policies

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MEDICAL POLICY

ADJUNCTIVE THERAPIES FOR THE HEALING OF DERMAL WOUNDS

Policy # 299
Implementation Date:2/15/06
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Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Dermal wounds are a major source of morbidity/mortality and lead to considerable disability. Acute wounds can result in the lengthening of hospitalization with associated risks for iatrogenic infections and other complications. The incidence of chronic wounds alone in the United States is approximately 5–7 million per year with the annual costs for management of these wounds estimated to be greater than $20 billion. In addition, chronic dermal wounds can lead to complications such as infections, contractures, depression, or limb amputation.

Various adjunctive therapies are available which can be used to assist in healing of acute and chronic wounds. These include electrical stimulation, high frequency pulsed magnetic stimulation, laser, heat, radiofrequency, and ultrasound therapies. These therapies are either applied to the wound area, or across the wound for a period. Each modality proposes to speed wound-healing through ill-defined effects on cell function or circulation in the area.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers electrical stimulation as an adjunct to dermal wound healing as its use in wound healing has been sufficiently demonstrated in the medical literature to show improvement in health outcomes.

Select Health does NOT cover high frequency pulsed magnetic therapy (e.g., Diapulse SofPulse), radiofrequency (e.g., The Provant Wound Closure System), laser therapy, heat therapy, or noncontact normothermic wound therapy (NNWT – e.g., the Warm-Up Active Wound Therapy System). These therapies meet the plan's definition of experimental/investigational.

Select Health does NOT cover ultrasound wound therapy for the treatment of wounds. Current evidence is weak as to the effectiveness of this technology in chronic wound management.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage,

please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Electrical stimulation**:** Twelve studies on the use of electrical stimulation for chronic wounds were identified. Of these, 10 were randomized controlled trials, 7 of which involved placebo or sham conditions in which wounds were treated with an inactive electrical unit or subtherapeutic levels of electrical stimulation. The studies primarily involved patients with diabetic wounds or stage II, III, IV pressure ulcers, and 2 studies involved wounds of various types.

This literature universally supports use of electrical stimulation in management of stage II, III, and IV pressure ulcers. Wood et al., for example, used a double blind, placebo-controlled trial to examine the effect of low-intensity direct current (300–600 microA) on healing of stage II and III pressure ulcers. After 8 weeks of therapy, 58% of the ulcers treated with electrical stimulation had healed compared with 3% of the placebo group ulcers, a statistically significant difference even after accounting for surface area and ulcer depth before treatment. Kloth and Feedar randomized 16 patients to electrical stimulation therapy or to sham treatment. The mean wound size decreased 45% ± 23% per week in the treatment group compared with a mean increase of 12% ± 18% per week for the control group. Furthermore, all ulcers that underwent electrical stimulation healed, on average, in 7.4 ± 4.2 weeks, while none of the ulcers in the control group healed during the study period.

Peters et al. reported similar success using electrical stimulation for diabetic wounds. In a randomized, double-blind, placebo-controlled pilot study, 65% of the wounds treated with high-voltage, pulse-galvanic electric stimulation healed in the 12-week follow-up, while 35% healed with the placebo treatment, though, this difference was not statistically significant. After stratifying by compliance, 71% of adherent patients in the treatment group healed compared with 39% of adherent patients in the placebo group. Similarly, Baker et al. improved wound healing in 80 patients randomized to 2 different electrical stimulation protocols, a low-intensity stimulation placebo, or a control group that underwent standard wound care. After 5–7 weeks, the patients who underwent asymmetric electrical stimulation had a mean weekly 27% ± 4% decrease in wound size compared to a 17% ± 2.7% mean decrease for the placebo and control groups.

Lundeberg et al., 64 patients with venous stasis ulcers were randomly assigned to electrical stimulation or a placebo and a statistically significant decrease in wound size was seen only after 12 weeks when the average ulcer area in the test group had decreased to 39% ± 14% of initial size vs. 59% ± 11% of initial size for the control group. After 12 weeks, there was also a statistically significant increase in the number of wounds that had healed completely: 10 (31%) in the test group vs. 4 (13%) in the control group.

Gardner et al.'s meta-analysis of 15 studies yielded an overall weekly healing rate of 22% for electrical stimulation and 9% for control therapies. The net effect of electrical stimulation was 13% per week, an increase of 144% over the control rate. Electrical stimulation was most effective on pressure ulcers (net effect = 13%).

The literature in this area suggests that electrical stimulation is a promising adjunct therapy that may improve wound healing rates and closure incidence in patients with advanced pressure ulcers, diabetic ulcers, and venous ulcers. Most of the data regarding its effectiveness come from randomized controlled trials, many of which utilized appropriate sham or placebo treatments as comparison. As with most studies in the wound care area, this literature involved primarily small patient samples (n ranged from 16 - 100). Many of these studies did not apply any inferential statistics to evaluate the reliability of their results. The greatest weakness of this literature is inconsistency in electrical stimulation protocols across studies. Protocols varied substantially in terms of the type of electrical stimulation, the frequency of treatment

sessions, and the duration of therapy. This heterogeneity severely limits any conclusions about which protocol is most effective in improving wound healing. Currently, there are not widely accepted, standard protocols for administering electrical stimulation for wound treatment.

High frequency pulsed electromagnetic stimulation: Six studies involving electromagnetic stimulation for wound healing are included here. Four of these focused on venous ulcer healing and the other 2 examined electromagnetic treatment for pressure ulcers. Five of the 6 studies were double-blind randomized placebo-controlled trials in which patients were randomly assigned to receive actual or sham electromagnetic stimulation adjunct to conventional wound care. The largest of these trials, Leran et al., reported that venous wound healing was significantly improved in the treatment group. Among treated patients, 25% experienced wound recurrence compared to 50% of the control group. Stiller et al. reported that venous ulcers with electromagnetic stimulation experienced a 47.7% decrease in wound surface area vs. a 42.3% increase for placebo. Investigators' blinded global assessment indicated that 50% of the treated ulcers healed or markedly improved vs. 0% of the placebo-treated ulcers; none of the treated ulcers worsened compared with 54% worsening in the placebo group. Salzburg examined stage II and III pressure ulcers and reported that the treated ulcers had experienced significantly greater healing and a shorter median healing time than did untreated ulcers. In contrast, Todd et al.'s study of 19 patients with venous ulcers found no difference between treated and placebo-treated wounds in terms of healing rates of the ulcer, change in the lower leg girth, pain, or infection rates.

The primary weakness of this literature is the lack of studies involving larger sample sizes. The strongest data from a few small studies suggest that high-frequency pulsed electromagnetic stimulation may improve healing rates in venous wounds, but larger randomized clinical trials are needed before definitive conclusions regarding its efficacy and safety can be made.

Radiofrequency (Provant): Only 1 study examining this treatment modality was located in this literature search. In this randomized placebo-controlled trial of 49 patients with Stage II or III pressure ulcers, wounds treated with Provant therapy experienced improved healing over wounds treated with a sham device. Specifically, at 12 weeks, 100% of stage II wounds and 50% of stage III treated with Provant had healed vs. 36% of stage II and 14% of stage III sham-treated wounds. The closure rate for Provant-treated wounds was 11.92 ± 2.0 mm^2/day and 12.9 ± 4.1 for stage II and III wounds, respectively, while the healing rate for stage II and III sham-treated wounds was 6.8 ± 1.7 and 3.6 ± 2.2, respectively.

The results of this trial suggest that Provant may promote healing for stage II and III pressure ulcers. However, more trials are needed to adequately evaluate the long-term safety and efficacy of this treatment modality for pressure ulcers and other dermal wounds.

Laser (pulsed monochromatic light) therapy: The literature included in this review includes 7 studies. These studies focused primarily on venous ulcers, though, 1 study included wounds of various etiologies and another examined pressure ulcer healing. The 5 randomized controlled trials involving sham treatment control groups universally concluded that laser therapy had no effect on wound closure or healing rates that was statistically significant. Interestingly, a meta-analysis published in 2004 concluded that laser therapy is effective in wound healing. However, this study combined animal and human studies in its analysis. While the overall effect size was highly significant, the effect size for studies involving only humans was marginal (d = 0.54). This analysis also combined healing for a variety of cutaneous and non-cutaneous wound types. Thus, the specific effect of laser therapy for cutaneous wounds cannot be determined from this study.

Noncontact normothermic wound therapy (Warm-Up Active Wound Therapy): Nine studies examining the use of noncontact normothermic wound therapy (NNWT) for wound healing were included in this literature review. Of these, 7 were randomized controlled trials, 1 was a prospective cohort study, and 1 examined the cost-effectiveness of NNWT relative to standard wound care. All of the studies involved homogenous samples of chronic wound patients and examined NNWT in stage III-IV pressure ulcers, venous leg ulcers, and diabetic foot ulcers. For all the studies, the primary outcome was wound closure rate with proportion healed as an additional primary outcome in four studies. One study measured time to healing as the primary outcome.

The published literature suggests that NNWT may accelerate wound closure over standard treatments in patients with stage III or IV pressure ulcers. For example, Kloth et al. reported that the wound healing rate in pressure ulcer patients was significantly greater in those receiving NNWT (0.52 cm^2/week) than for the control group (0.23 cm^2/week) after 8 weeks of therapy. The incidence of closure among wounds that

completed the entire 12-week protocol was 79% (11 of 14) in NNWT patients and 50% in controls, though, this difference was statistically nonsignificant. Whitney et al. reported a significantly faster closure rate and Thomas et al. reported a higher proportion of healing in pressure ulcer patients treated with NNWT over standard wound care. Similar therapeutic results have been observed in patients with diabetic foot ulcers: NNWT can improve healing rates and the incidence of complete healing over standard wound therapy. Two studies examined NNWT in treatment for venous wounds. Robinson and Santilli's report of patients with venous wounds described greater decreases in wound size in NNWT patients over those treated with standard therapy, although the pre-study wound size was significantly higher in the treatment group (64.4 ± 23 cm^2 vs. 29.4 ± 14cm^2). Another prospective cohort study of 17 patients reported improved wound healing after 2 weeks and complete wound closure in 47% of patients after 18 months.

The literature in this area suggests that NNWT is a promising therapy that may improve wound healing rates and closure incidence in patients with advanced pressure ulcers, diabetic ulcers, and venous ulcers. However, several design and statistical issues limit conclusions about the short- and long-term effectiveness of this treatment modality. All the studies in this area involved relatively small samples (n ranged from 13–41). Furthermore, few of these studies applied any inferential statistical analysis to evaluate the reliability of their results and none utilized any procedures to blind patients or study staff to the treatment conditions. Finally, none of the studies utilized sham or placebo treatments and follow-up was confined to a fairly short time frame, typically 8–12 weeks.

Therapeutic ultrasound therapy (MIST Therapy System and Qoustic Wound Therapy System [AR1000])

Six systematic reviews examining therapeutic ultrasound (TU) for a variety of indications were identified. Two Cochrane reviews examined TU for venous leg ulcers and pressure ulcers. The 2006 review, by Baba-Akbari Sari et al., identified 3 trials involving a total of 146 patients with pressure ulcers. Two compared TU to sham therapy, and the third compared ultrasound and ultraviolet light with laser and with standard treatment. None of these studies found any statistically significant difference in wound outcomes between TU and controls, leading the authors to conclude that there is no evidence of benefit or harm of ultrasound therapy in the treatment of pressure ulcers due to the small number of trials, some with methodological limitations and small numbers of participants. In 2008, Al-Kurdi reviewed 8 trials of TU for venous leg ulcers. Five trials compared ultrasound therapy with sham ultrasound; 3 trials compared ultrasound therapy with standard treatment. No trials individually found a statistically significant difference in the number of ulcers healed but some reported that TU increases the rate of change of wound size. Pooled analyses suggested that TU healed more ulcers completely, however, and confirmed that TU reduces the size of existing ulcers. The authors concluded that TU may increase healing of venous leg ulcers, but they suggested caution as their conclusions were based on the results of eight small studies of generally poor quality.

Three reviews examined TU among multiple alternatives for treating chronic wounds. A 2001 review by Cullum et al. on behalf of the UK Public Health Service examined a variety of chronic wound therapies including TU. That review identified 10 studies on TU for pressure sores and venous leg ulcers and the reviewers concluded that there is generally insufficient reliable evidence to draw conclusions about the contribution of TU in wound healing. A similar review in 2008 by Hinchcliffe et al. offered the same conclusions about TU for diabetic foot ulcers. The authors' strongly worded conclusion observed some support for using negative pressure wound therapy and surgical excision but: "… no data were found to justify the use of any other topically applied product or dressing. Further evidence to substantiate the effect of interventions designed to enhance the healing of chronic ulcers is urgently needed. Until such evidence is available from robust trials, there is limited justification for the use of more expensive treatments and dressings." A 2008 review by Reddy et al. of treatments for pressure ulcers found one randomized controlled trial for TU. Based on this single comparative trial, the authors concluded that there are limited data to support routine use of these expensive adjunctive therapies (including TU) in managing pressure ulcers.

Finally, a 2008 review by Ramundo et al. specifically examined the efficacy of MIST therapy for debridement of chronic wounds. They systematically reviewed the literature from January 1996 to February 2008 and found insufficient evidence to determine whether ultrasonic MIST therapy effectively debrides necrotic tissue in chronic wound beds.

Adjunctive Therapies for the Healing of Dermal Wounds, continued

In addition to the systematic reviews, 22 empirical studies met criteria. Most of these were small, nonrandomized case series without a comparison group. One new comparative trial was identified that was published since the systematic reviews. Dolibog et al. examined TU in 70 patients with venous leg ulcers. Patients were randomly assigned to either compression therapy with stockings or to compression with TU (5 days after surgical intervention) once daily for 6 days a week over 7 weeks. At the end of treatment, the relative change of the total surface area (60.01% vs. 60.06%), length (39.9% vs. 43.01%), width (42.76% vs. 46.22%), and volume (80.33% vs. 82.41%), did not demonstrate any difference between the treatment and control groups, respectively.

None of the systematic reviews offer strong support for TU as treatment for chronic wounds. The only positive finding in these reviews was Al Kurdi's pooled analysis that revealed a modest advantage for TU over standard therapy. Lower extremity ulcers, particularly venous ulcers, have received the bulk of the research on TU published to date. A surprising number of randomized trials have been published, most in support of TU as an adjunct to standard therapies. However, the sample sizes in these studies are too small to permit generalization of findings to larger patient populations. Though the findings are statistically significant, they are more prone to Type I errors due to these smaller sample sizes. Thus, conclusions based on these studies are limited. Overall, the literature offers modest support for TU (including MIST and Quostic) in treatment of venous ulcers of the lower extremities but there is no support in the literature for this treatment for any other indication.

Billing/Coding Information

CPT CODES

Covered: For the conditions outlined above

Electrotherapy - Electrical Stimulation for Chronic Ulcers

97014	Application of a modality to one or more areas; electrical stimulation (unattended)
97032	Application of a modality to one or more areas; electrical stimulation (manual) (one-on-one by provider) each 15 minutes.

Not covered: Experimental/Investigational/Unproven for this use

Therapeutic Ultrasound Therapy

97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day

HCPCS CODES

Covered: For the conditions outlined above

Electrotherapy - Electrical Stimulation for Chronic Ulcers

G0281	Electrical stimulation, (unattended), to one or more areas, for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a therapy plan of care
E0769	Electrical stimulation or electromagnetic wound treatment device, not otherwise classified

Not covered: Investigational/Experimental/Unproven for these indications

High-Frequency Pulsed Electromagnetic Stimulation

G0329	Electromagnetic therapy, to one or more areas for chronic State III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care.
E0769	Electrical stimulation or electromagnetic wound treatment device, not otherwise classified
E0761	Non-thermal pulsed high-frequency radio waves, high peak power electromagnetic energy treatment device

Laser Therapy - Low-Level Laser or Cold Laser Therapy

S8948 Application of modality (required constant provider attendance) to one or more area; low-level laser; each 15 minutes

Non-contact Normothermic Wound Therapy (NNWT)

A6000 Non-contact wound warming cover for use with the non-contact wound warming device and warming card

E0231 Non-contact wound warming device (temperature control unit, AC adaptor and power cord) for use with warming card and wound cover

E0232 Warming care for use with the non-contact wound warming device and non-contact wound warming cover

Radiofrequency - Provant Wound Closure System

E0761 Non-thermal pulsed high-frequency radio waves, high peak power electromagnetic energy treatment device

G0329 Electromagnetic therapy, to one or more areas for chronic State III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care

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Adjunctive Therapies for the Healing of Dermal Wounds, continued

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MEDICAL POLICY

BENIGN SKIN AND SUBCUTANEOUS LESIONS

Policy # 103

Implementation Date:7/1/98

Review Dates: 9/18/00, 11/1/01, 8/28/02, 6/25/03, 9/8/03, 10/23/03, 6/24/04, 5/17/05, 5/3/06, 5/17/07, 4/24/08, 4/23/09, 4/22/10, 9/23/11, 11/29/12, 10/24/13, 10/14/14, 10/15/15, 10/20/16, 11/27/18, 12/18/19, 12/17/20, 12/15/21, 1/13/23, 12/22/23, 11/29/24

Revision Dates: 9/8/03, 9/23/11, 2/8/17, 6/5/17

Related Medical Policies:

#168 Laser Treatment of Congenital Hemangiomas (Port Wine Stains)

#231 Treatment of Keloids

#237 Cryosurgical Ablation of Plantar Fasciitis, Morton's Neuromas and other Conditions of the Feet

#424 Sclerotherapy for the Management of Lymphangiomata

Disclaimer:
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2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Adult patients frequently seek removal of skin lesions that cause them to feel concern about possible skin malignancies such as malignant melanoma, atypical nevi (dysplastic nevi), squamous cell carcinoma, basal cell carcinoma, and other non-melanoma skin cancers. However, these lesions may be found to be benign, non-malignant lesions. Subsequently, after evaluation/removal non-covered treatment codes are sometimes used. This can lead to the denial of claims for services.

A lipoma is a benign fatty tumor usually composed of mature fat cells, that can involve the dermis, epidermis, and subcutaneous tissues, and is rarely found below the fascia (i.e., sub-fascial and sub-muscular). Most of these lesions are below the skin (dermis) but above the fascia.

Additionally, patients also often seek treatment for known, benign skin lesions such as 'skin tags' due to symptoms of skin irritation, pain, recurrent infections or changing character of the lesion.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers the removal of lipomas, seborrheic keratoses, melanocytic nevi, acrochordons/skin tags, fibromas, and dermatofibromas in adults when found to be medically necessary based upon documentation of a functional* problem.

Some benign skin conditions present predominantly in children such as congenital hemangiomas, port wine stains, and other vascular lesions, which may only be covered under specific conditions identified in policies specific to those conditions.

Specific lesions not shown to have a covered functional* problem are denied, based on the reconstructive and cosmetic limitations present in the plan certificate of coverage.

Benign Skin and Subcutaneous Lesions, continued

*Functional impairment is defined as symptoms of such magnitude, or locations of the lesion, that it impairs an individual's ability to perform ADLs, limits mobility, or otherwise prevents normal function of a body part. Symptoms may include, but are not limited to, pain, tenderness, itch (pruritus), ulceration, bleeding, frequent irritation, active inflammation, and restriction of movement to avoid symptoms.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

The skin is an anatomically complex organ subject to the occurrence of a wide spectrum of nevi and neoplasms that may be malignant, potentially malignant, or benign. Diagnosis and treatment of benign or potentially malignant skin lesions requires significant expertise. Although many of these skin lesions do not need treatment, some benign or potentially malignant nevi and neoplasms, cysts, or reactive lesions require medical or surgical intervention for accurate clinical and/or histological diagnosis, to rule out malignancy, to treat or prevent complications, such as infection, ulceration, bleeding, or further enlargement of the lesion, for relief of symptoms of irritation, tenderness, or pain, for avoidance or correction of disfigurement, to prevent progression to frank malignancy, or to rule out benign infiltrative or other reactive processes.

If there is a question of diagnosis or possible malignancy, one or more lesions are submitted for histological evaluation. In some cases, special stains, histochemical or immunohistochemical staining, or microbiologic techniques may be needed. Occasionally electron microscopy may give additional information.

In the case in which the patient has multiple lesions known to be benign (e.g., multiple seborrheic keratosis, multiple fibroepitheliomas, papillomas [skin tags], and others), removal or destruction without biopsy of all lesions is customary practice.

Accurate diagnosis and proper management of benign, potentially malignant, or premalignant skin lesions often require significant expertise. Physicians should be familiar with the clinical presentation of these lesions, and it is often helpful to correlate the clinical presentation (the "gross pathology") with the histological changes (the "microscopic pathology") in these lesions and disorders.

The treatment will vary depending on multiple factors, including lesion type and location and may include the medical treatments such as topical or systemic medications, intralesional injections, radiotherapy or surgical treatments such as excision, shave biopsy, shave removal, saucerization, destruction using cryotherapy, electrocautery, or chemical or laser therapy. Dermabrasion and liposuction are also methods used to treat these conditions but are generally used only for cosmetic advantage not for any improved outcome over other methods of removing the lesions. Except under unusual circumstances (e.g., large size, multiplicity of lesions, location in anatomically sensitive body areas, and prior medical or psychological condition of the patient or other unusual circumstances) management of benign, potentially malignant, or premalignant lesions is usually carried out in private physician offices or outpatient clinics. Patients with certain medical conditions such as those with cardiopulmonary problems in which close monitoring are indicated may be admitted to an ambulatory surgical center or hospital.

Benign Skin and Subcutaneous Lesions, continued

Billing/Coding Information
Covered: For the conditions outlined above

CPT CODES

11400	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 0.5 cm or less
11401	; excised diameter 0.6 to 1.0 cm
11402	; excised diameter 1.1 to 2.0 cm
11403	; excised diameter 2.1 to 3.0 cm
11404	; excised diameter 3.1 to 4.0 cm
11406	; excised diameter over 4.0 cm
11420	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 0.5 cm or less
11421	; excised diameter 0.6 to 1.0 cm
11422	; excised diameter 1.1 to 2.0 cm
11423	; excised diameter 2.1 to 3.0 cm
11424	; excised diameter 3.1 to 4.0 cm
11426	; excised diameter over 4.0 cm
11440	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 0.5 cm or less
11441	; excised diameter 0.6 to 1.0 cm
11442	; excised diameter 1.1 to 2.0 cm
11443	; excised diameter 2.1 to 3.0 cm
11444	; excised diameter 3.1 to 4.0 cm
11446	; excised diameter over 4.0 cm
21011	Excision, tumor, soft tissue of face or scalp, subcutaneous; less than 2 cm
21012	: 2 cm or greater
21552	Excision, tumor, soft tissue of neck or anterior thorax, subcutaneous; 3 cm or greater
21555	; less than 3 cm
21930	Excision, tumor, soft tissue of back or flank, subcutaneous; less than 3 cm
21931	; 3 cm or greater
22902	Excision, tumor, soft tissue of abdominal wall, subcutaneous; less than 3 cm
22903	; 3 cm or greater
23071	Excision, tumor, soft tissue of shoulder area, subcutaneous; 3 cm or greater
23075	; less than 3 cm
24071	Excision, tumor, soft tissue of upper arm or elbow area, subcutaneous; 3 cm or greater
24075	; less than 3 cm
25071	Excision, tumor, soft tissue of forearm and/or wrist area, subcutaneous; 3 cm or greater
25075	; less than 3 cm
26111	Excision, tumor or vascular malformation, soft tissue of hand or finger, subcutaneous; 1.5 cm or greater

Benign Skin and Subcutaneous Lesions, continued

26115	; less than 1.5 cm
27043	Excision, tumor, soft tissue of pelvis and hip area, subcutaneous; 3 cm or greater
27047	; less than 3 cm
27327	Excision, tumor, soft tissue of thigh or knee area, subcutaneous; less than 3 cm
27337	; 3 cm or greater
27618	Excision, tumor, soft tissue of leg or ankle area, subcutaneous; less than 3 cm
27632	; 3 cm or greater
28039	Excision, tumor, soft tissue of foot or toe, subcutaneous; 1.5 cm or greater
28043	; less than 1.5 cm

If a lipoma is below the epidermis, dermis, and subcutaneous layers of skin (i.e., in a sub-fascial or a sub-muscular tissue) the appropriate codes are listed below:

21013	Excision, tumor, soft tissue of face and scalp, subfascial (eg, subgaleal, intramuscular); less than 2 cm
21014	; 2 cm or greater
21554	Excision, tumor, soft tissue of neck or anterior thorax, subfascial (eg, intramuscular); 5 cm or greater
21556	; less than 5 cm
21932	Excision, tumor, soft tissue of back or flank, subfascial (eg, intramuscular); less than 5 cm
21933	; 5 cm or greater
22900	Excision, tumor, soft tissue of abdominal wall, subfascial (eg, intramuscular); less than 5 cm
22901	; 5 cm or greater
23073	Excision, tumor, soft tissue of shoulder area, subfascial (eg, intramuscular); 5 cm or greater
23076	; less than 5 cm
24073	Excision, tumor, soft tissue of upper arm or elbow area, subfascial (eg, intramuscular); 5 cm or greater
24076	; less than 5 cm
26113	Excision, tumor, soft tissue, or vascular malformation, of hand or finger, subfascial (eg, intramuscular); 1.5 cm or greater
26116	; less than 1.5 cm
27045	Excision, tumor, soft tissue of pelvis and hip area, subfascial (eg, intramuscular); 5 cm or greater
27048	; less than 5 cm
27328	Excision, tumor, soft tissue of thigh or knee area, subfascial (eg, intramuscular); less than 5 cm
27339	; 5 cm or greater
27619	Excision, tumor, soft tissue of leg or ankle area, subfascial (eg, intramuscular); less than 5 cm
27634	; 5 cm or greater
28041	Excision, tumor, soft tissue of foot or toe, subfascial (eg, intramuscular); 1.5 cm or greater

Benign Skin and Subcutaneous Lesions, continued

28045 ; less than 1.5 cm

HCPCS CODES

No specific codes identified

Key References

1. American Academy of Dermatology: Referral Guidelines for approach to the treatment of non-melanocytic nevi, hematoma, neoplasms, and other potentially neoplastic lesions/95

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MEDICAL POLICY

CELLULAR AND/OR TISSUE-BASED PRODUCTS (CTP)

Policy # 227

Implementation Date:5/1/04

Review Dates: 4/14/05, 6/22/06, 5/17/07, 4/24/08, 4/23/09, 5/19/11, 6/20/11, 6/20/13, 4/17/14, 10/20/16, 10/19/17, 10/25/18, 10/7/19, 10/14/20, 11/27/21, 9/15/22, 10/10/23, 10/11/24

Revision Dates: 2/24/05, 2/18/10, 4/21/15, 7/18/18, 12/31/19, 10/1/20, 10/14/21, 10/14/22, 4/7/23

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Cellular and/or tissue-based products (CTP), also referred to as synthetic skin substitutes, are tissue-engineered products using living cells, such as fibroblasts and keratinocytes, in a scaffold of natural or synthetic extracellular matrices. These matrices provide mechanical stability and a three-dimensional framework for eventual tissue infiltration and development; and can also promote wound healing by stimulating the host to produce a variety of cytokines. Scaffolds are characterized as biodegradable, natural, or synthetic. Synthetic scaffolds, such as polyglycolic acid and polyglactic acid, are often manufactured on a large scale.

Tissue-engineered skin substitutes can be broadly categorized into epidermal components alone, mainly dermal components, or composite grafts (containing both epidermal and dermal components). Epidermal skin substitutes consist of grafts of cultured epidermal cells with no dermal components. These products are often characterized by prolonged culture time and handling difficulties. Dermal skin substitutes help prevent wound contraction and offer greater mechanical stability. Numerous products have been developed for various applications.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers *certain* synthetic skin substitutes as the medical literature has demonstrated use of this technology to be a cost-effective alternative to standard therapies, and which have also demonstrated improvement in the health outcomes of patients.

Select Health covers the following synthetic skin substitutes:

1- AlloDerm
2- AlloSkin
3- Alloskin RT
4- Apligraf
5- Arthroflex
6- Cortiva
7- Cymetra
8- Cytal
9- DermACELL

Cellular and/or Tissue-based Products (CTP), continued

10- Dermagraft
11- Epifix (Non-injectable)
12- Epiburn
13- FlexHD, AllopatchHD, Matrix HD
14- GammaGraft
15- Grafix
16- GraftJacket
17- Hyalomatrix
18- Innovamatrix
19- Integra bilayer matrix wound dressing
20- Integra dermal regeneration template
21- Integra flowable wound matrix
22- Integra Matrix
23- MatriStem micromatrix
24- MemoDerm, DermaSpan, TranZgraft, or IntéguPlyOasis burn matrix
25- Novafix
26- Oasis wound matrix
27- Oasis ultra tri-layer wound matrix
28- Phasix Mesh/Phasix ST Mesh
29- PriMatrix
30- Restrata
31- Talymed
32- TheraSkin

All other synthetic skin substitutes not mentioned above, and with no specific HCPCS code, will be considered investigational/experimental, and therefore, will not be covered.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

This topic was thoroughly reviewed in the Hayes Report dated February 2004. This review covered a myriad of skin substitutes currently available, identifying those that have shown positive outcomes with regards to wound healing in difficult and complex patients and those with inadequate literature support to address outcomes. This study identified that some evidence from a limited number of randomized controlled trials demonstrates that Apligraf can improve the speed of healing and complete healing rate in patients with chronic venous ulcers. There is also evidence from randomized controlled trials that both

Cellular and/or Tissue-based Products (CTP), continued

Apligraf and Dermagraft can improve healing of diabetic foot ulcers that have failed standard wound care. These skin substitutes are used in conjunction with standard wound care and are not considered first-line therapy; they are used in patients who have not responded adequately to appropriate standard therapy. There is also some evidence to support the use of these and other skin substitute products in patients with other types of wounds, such as thermal burns, skin graft donor site wounds, and acute surgical wounds. However, the evidence regarding these other indications is very limited and of lesser quality, and additional randomized controlled studies will be required to establish the safety and efficacy of skin substitutes for other types of wounds and to define appropriate patient selection criteria.

An additional economic analysis by Schonfeld et al. published in 2000 indicates the cost effectiveness of the use of this technology, specifically Apligraf. This provides further support for the use of skin substitutes. This study is limited in its generalization, as only the Apligraf skin substitute was evaluated, and the comparison was made to conservative therapy rather than other skin grafting options. Nonetheless, this provides evidence to support use of these technologies.

Information derived from the Hayes February 2004 Review regarding specific synthetic skin substitute reveals the following:

AlloDerm: The safety and efficacy of AlloDerm was evaluated in two studies, including one small, randomized trial and one somewhat larger uncontrolled study. Both studies involved patients with burns; AlloDerm was used either in conjunction with a thin allograft or was used to cover the donor site. Results were positive and demonstrated that this skin substitute may speed healing and reduce scar formation in patients who require skin grafting. However, these were both small studies and do not provide definitive proof that AlloDerm is superior to conventional grafting or enough evidence to define patient selection criteria.

Apligraf: The strongest evidence regarding the efficacy of the different skin substitutes is for the use of Apligraf in the treatment of chronic venous leg ulcers. Results of three randomized trials suggest that Apligraf can significantly reduce the time to complete healing of chronic venous leg ulcers compared with standard treatment. In one study, Apligraf was significantly more effective than compression therapy for patients with large ulcers (> 1000 mm2), patients with deeper ulcers, and patients with ulcers of > 6 months' duration. However, in the same study, standard compression was as efficacious as Apligraf combined with compression therapy in a subgroup of patients with venous ulcers of < 6 months' duration, suggesting that the most benefit of Apligraf is for patients with large or deep ulcers and for patients with chronic ulcers. One author stated that Apligraf is not recommended for first-line therapy since most patients with small, noninfected ulcers of short duration would be expected to heal by compression therapy alone.

There was also relatively good, albeit limited, evidence from two randomized controlled studies that demonstrated efficacy of Apligraf in the healing of diabetic foot ulcers. Both studies found that treatment with Apligraf significantly increased the complete wound healing rate in patients with diabetic foot ulcers. Even though Apligraf has been investigated in a number of patients with acute excisional wounds, the evidence to support the routine use of Apligraf in these patients is weak. In a multicenter, uncontrolled trial of patients with acute excisional wounds that would otherwise require grafting or healing by secondary intention (n=110), Apligraf was well-tolerated, and showed no signs of clinical rejection, and performed as well as or better than autografts in approximately 50% of patients.

However, these findings were based on subjective impressions, with no analysis of the reliability of the responses. In a pair comparison, randomized controlled trial (n=20) comparing the efficacy of Apligraf for healing acute, partial-thickness donor site wounds with that of autografts and polyurethane film occlusive dressings, the time to complete healing, pain relief, and cosmetic outcomes were similar for sites treated with Apligraf and autograft, whereas polyurethane film resulted in a longer time to healing and a poorer cosmetic outcome. However, due to the preliminary nature and the small size of this study, the relevance of the results to other patient populations cannot be readily determined. Additional data from well-designed trials are needed before definitive conclusions can be reached. In one study of patients with acute excisional wounds, the clinical persistence of Apligraf, which was determined subjectively, decreased over time. This was partially attributed to the inability of the investigators to determine whether allograft had replaced the patient's skin or whether the patient's skin had replaced the allograft. The possible occurrence of silent rejection (i.e., the replacement of the allograft by host tissue) indicates a

need for additional studies to evaluate this phenomenon at the cellular level in order to fully resolve questions about graft take and rejection.

Biobrane/Biobrane-L: Two studies, one large uncontrolled study and one small, randomized study, demonstrated significantly reduced pain and shorter hospital stay in pediatric patients with scald burn wounds. The larger, uncontrolled trial, however, failed to delineate outcome measures and procedures related to methodology. Researchers did not provide clear measurement of pain assessment and compelling comparisons of hospital length of stay. Also, in patients with deep partial-thickness burns, the rate of infection was significantly higher than the rate of infection in patients with superficial partial-thickness burns. Further research is needed to explore the limited resistance of infection in more severely burned patients treated with Biobrane/Biobrane-L.

Dermagraft: The evidence regarding the efficacy of Dermagraft for treatment of diabetic foot ulcers is relatively good, although limited. Two randomized controlled trials, one of which involved 50 patients and the other of which included over 300 patients, both reported faster and more complete healing of chronic diabetic foot ulcers, compared with standard treatment. Additional study is required to define further patient selection criteria for Dermagraft, particularly with regards to ulcer duration and location.

Epifix: One systematic review and 10 primary studies published between 2012 to 2014, demonstrated Epifix to be of similar efficacy and safety as alternative substitutes. The published studies identified no significant safety issues such as aberrant tissue reactions or other issues. The studies demonstrate efficacy comparable if not potentially superior to some other graft materials. Limitations to any conclusions regarding the comparative efficacy of these therapies stems from a lack of comparative trials of various skin substitutes.

Several EpiFix studies attempted to provide comparative effectiveness to commonly used skin substitutes, Dermagraft and Apligraf. The studies suggest EpiFix has better 12-week closure rates than either Dermagraft or Apligraf as well as lower ulcer recurrence rates.

The important question of how EpiFix compares to Apligraf and dressings was addressed by Zelen et al. in a 2014 study of 60 patients. EpiFix improved outcomes significantly more than the Apligraf and dressings group. This was the only study to compare these three treatments. The literature on EpiFix, overall, is favorable related to outcomes though there exists a lack of comparative studies for most alternative skin substitutes. It is important to note, however, that all the literature is published by the manufacturer which may bias some of the outcomes. Current evidence, however, suggests EpiFix improves outcomes above-and-beyond standard dressings and conventional allografts.

Integra: Evidence regarding the efficacy of Integra for treatment of acute burn wounds is relatively weak. Results of a randomized, matched-pair comparison trial suggested that Integra provided a permanent cover that was at least as satisfactory as other skin graft techniques, with less hypertrophic scarring than control grafts. However, infection was evident in several patients. In a more recent but smaller randomized trial, Integra demonstrated poor resistance to infection, and the trial was prematurely terminated due to deaths attributable to infection. Results of a retrospective study and a prospective uncontrolled trial suggested that the use of Integra was safe and effective in patients with acute burns and was associated with decreased hospital stay; however, both studies lacked blinding, randomization, and adequate study populations.

Evidence for the use of Integra template for reconstructive surgery is limited and currently includes only case series studies. These uncontrolled studies demonstrated positive outcomes with Integra use, such as substantial minimization of postoperative contracture and good aesthetic and functional outcomes. Patient and physician satisfaction ranked high, although these subjective outcomes were not fully analyzed for reliability.

OrCel: Only 1 randomized trial evaluating OrCel was available in the literature. This study compared OrCel with Biobrane-L for donor site wounds in patients who were undergoing skin grafting for acute burn injuries. The study found that OrCel stimulated greater skin regeneration and wound healing, and less scarring, compared with Biobrane-L.

TransCyte/Dermagraft-TC: Three small, randomized controlled studies reported on the safety and efficacy of TransCyte/ Dermagraft-TC in treating patients with moderate to deep partial-thickness burn wounds. These studies provided some evidence that TransCyte was effective in reducing pain, with an increased rate of re-epithelialization in serious burn wounds; however, results were limited by small study

populations and short follow-up periods. Complications attributed to the use of skin substitute products were relatively rare in the literature; infection was the most frequently reported complication, although in most studies, wound infection occurred at a comparable rate in patients treated with standard therapy alone.

Definitive patient selection criteria for the use of skin substitutes for wound healing have not been established. However, there is sufficient evidence to conclude that the use of Apligraf combined with standard wound care can improve healing in patients with chronic venous and diabetic foot ulcers. There is also sufficient evidence to support the use of Dermagraft in patients with chronic diabetic foot ulcers. These conclusions assume that patients have had an inadequate response to appropriate standard wound therapy. The use of skin substitutes is contraindicated in patients with evidence of arterial occlusive disease, i.e., ankle-brachial index (ABI) > 0.65, infection in ulcer(s) targeted for treatment, exudate consistent with heavy bacterial contamination, or eschar or necrotic tissue that would interfere with graft take and healing, active Charcot's disease, or hypersensitivity or allergy to any components of the skin substitute product or packaging medium. The efficacy and safety of skin substitutes in patients who are pregnant or lactating, have uncontrolled diabetes, or are currently being treated with corticosteroids, immunosuppressant's, or chemotherapy have not been established.

Billing/Coding Information

CPT CODES

Covered: For the conditions outlined above

15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15272	; 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
15273	; greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15274	; greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15276	; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
15277	; greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15278	; greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

Repair of anorectal fistula with plug (e.g., Biodesign (Surgisis) AFP Anal Fistula Plug, GORE BIO-A Fistula Plug)

46707	Repair of anorectal fistula with plug (e.g.: porcine small intestine submucosa [SIS])

HCPCS CODES

A2001	Innovamatrix AC, per sq cm
A2007	Restrata, per sq cm
A2013	Innovamatrix FS, per sq cm

Cellular and/or Tissue-based Products (CTP), continued

A2026	Restrata minimatrix, 5 mg
C1781	Mesh (Implantable) – (ie, Davol Synthetic Mesh, AlloMax™ Surgical Graft, Phasix™ Mesh, Phasix™ ST Mesh, XenMatrix™ Surgical Graft and XenMatrix™ AB Surgical Graft)
C5271	Application of low cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
C5272	; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)
C5273	; greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
C5274	; greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
C5275	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
C5276	; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)
C5277	Application of low cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
C5278	; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (list separately in addition to code for primary procedure)
Q4100	Skin substitute, not otherwise specified
Q4101	Apligraf, per sq cm
Q4102	Oasis wound matrix, per sq cm
Q4103	Oasis burn matrix, per sq cm
Q4104	Integra bilayer matrix wound dressing (BMWD), per sq cm
Q4105	Integra dermal regeneration template (DRT) or Integra Omnigraft dermal regeneration matrix, per sq cm
Q4106	Dermagraft, per sq cm
Q4107	GRAFTJACKET, per sq cm
Q4108	Integra matrix, per sq cm
Q4110	PriMatrix, per sq cm
Q4111	GammaGraft, per sq cm
Q4112	Cymetra, injectable, 1 cc
Q4113	GRAFTJACKET XPRESS, injectable, 1cc
Q4114	Integra flowable wound matrix, injectable, 1 cc
Q4115	AlloSkin, per sq cm

Cellular and/or Tissue-based Products (CTP), continued

Q4116	AlloDerm, per sq cm
Q4117	HYALOMATRIX, per sq cm
Q4118	MatriStem micromatrix, 1 mg
Q4121	TheraSkin, per sq cm
Q4122	DermACELL, per sq cm
Q4123	AlloSkin RT, per sq cm
Q4124	OASIS ultra tri-layer wound matrix, per sq cm
Q4125	Arthroflex, per sq cm
Q4126	MemoDerm, DermaSpan, TranZgraft or InteguPly, per sq cm
Q4127	Talymed, per sq cm
Q4128	FlexHD, AllopatchHD, or Matrix HD, per sq cm
Q4132	Grafix core, per sq cm
Q4133	Grafix prime, per sq cm
Q4141	Alloskin AC, per sq cm
Q4166	Cytal, per sq cm
Q4186	Epifix, per sq cm
Q4208	Novafix, per sq cm
Q4254	Novafix DL, per sq cm

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Cellular and/or Tissue-based Products (CTP), continued

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Revision History

Revision Date	Summary of Changes
4/7/23	For Commercial Plan Policy, removed Flower AmnioPatch from the list of eligible synthetic skin substitutes available for coverage, and added Innovamatrix and Restrata to the list of eligible synthetic skin substitutes available for coverage.

Select Health

Select Health

MEDICAL POLICY

THERAPY FOR HYPERTROPHIC/KELOID SCARS

Policy # 231
Implementation Date:6/10/04
Review Dates: 8/25/05, 8/17/06, 8/23/07, 8/21/08, 8/13/09, 8/19/10, 9/15/11, 11/29/12, 10/24/13, 10/23/14, 10/15/15, 10/20/16, 10/19/17, 10/1/18, 10/15/19, 10/15/20, 11/17/21, 9/14/22, 10/13/23, 10/8/24
Revision Dates: 8/28/06, 5/10/16, 12/30/19, 8/15/23, 11/6/23, 3/20/24

Related Medical Policies:

#103 Benign Skin and Subcutaneous Lesions

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Keloids are benign fibrous growths that arise from proliferation of dermal tissue following skin injury. Keloids are common (keloids develop in 5%−15% of wounds). Conventional treatment options for keloids are occlusive dressings (including silicone-based materials), compression therapy, intralesional injections of corticosteroid, cryosurgery, and excision surgery. Newer modalities include the carbon dioxide, Nd:YAG, argon lasers, pulsed dye laser, intralesional interferon-gamma and interferon-alfa 2b, as well as cultured epithelial autografts. The incidence of recurrence is rather high following conventional forms of treatment. In particular, the recurrence rate of keloids after excision alone has been reported to be between 45%−100%. It has also been found that the recurrence rate following excision is higher with keloids forming at infected sites and in patients with a family history. Moreover, there is no increased likelihood of recurrence with respect to patient age, sex, or ethnicity; or keloid size or location, individual keloid history, or prior therapy used (in general, various lasers have produced similar recurrence rates as conventional surgery).

The pulsed dye laser delivers energy at a wavelength and duration that has been optimized for the selective treatment of vascular lesions. It has been used in the treatment of warts, port-wine stains, hemangiomas, hypertrophic scars, keloid scars, and telangiectasias. Pulsed dye lasers have been used as an alternative to surgical excision or carbon dioxide lasers. The Food and Drug Administration (FDA) has cleared the pulsed-dye laser for use in treatment of warts, port-wine stains, hemangiomas, hypertrophic scars, keloid scars, and telangiectasias.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health may cover superficial radiation therapy of symptomatic keloids following excisional surgery, when the patient has failed conservative therapy*; fraction standards are as follows:18−19 Gy in 3 fractions (earlobe) or 23−25 Gy in 3 fractions (non-earlobe).

Select Health covers laser therapy for the treatment of symptomatic hypertrophic or keloid scars in *limited circumstances* for patients who have failed conservative therapy*.

*Conservative therapy should include at least a 3-month trial of one of the following:

a) Corticosteroid tape or plaster
b) Corticosteroid injection

Laser Therapy for Keloids and Hypertrophic Scars, continued

c) Topical steroid ointment or cream
d) 5-flouraracil intralesional steroid injections
e) Cryotherapy

Select Health does NOT cover intralesional interferon alfa injections for the treatment of hypertrophic or keloid scars as available evidence for the efficacy of this therapy is weak and conflicting. This treatment meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

The precise pathogenesis of keloid formation is unknown. For some reason, certain individuals, most commonly African Americans and other ethnicities with darker skin tones, develop a hyperproliferation of fibroblasts in response to trauma, or, less commonly, de novo. Any skin insult (e.g., ear piercing, lacerations, secondarily infected skin lesions, acne, surgery, etc.) can cause keloid formation in predisposed individuals.

Alteration of apoptosis (programmed cell death) and cell proliferation have been implicated in the pathogenesis of keloids. In one study that compared the expression of 64 apoptosis-related genes in keloids and normal scars, under-expression of 8 of these genes was found in the fibroblasts derived from keloid tissue. The authors suggested that keloid fibroblasts fail to undergo physiologically programmed cell death, and therefore, continue to produce connective tissue beyond the period expected for normal scars. Others have come to similar conclusions. Overactivation of signals for insulin-like growth factor-I have also been implicated in the pathogenesis of keloids.

The diagnosis is based upon the clinical appearance of excessive scar tissue. Patients may be asymptomatic, but frequently have lesions that are pruritic, tender to palpation, or a source of sharp, shooting pains. Most commonly keloids occur on the ears, neck, jaw, presternal chest, shoulder girdle area, but can occur in any location, particularly in predisposed individuals. Another clinic example of a dermatologic condition leading to keloid formation is acne keloidalis nuchae, which refers to inflamed pustules and papules on the posterior neck that often heal with keloid formation.

Hypertrophic scars may initially appear similar to keloids, but in contrast to the latter, hypertrophic scars do not extend beyond the margins of the original skin injury or insult. While the treatment strategies are similar for both lesions, hypertrophic scars are less likely to recur once treated.

The best treatment is prevention in patients with a known predisposition. This includes preventing unnecessary trauma or surgery (including ear piercing, elective mole removal), whenever possible. Any skin problems in predisposed individuals (e.g., acne, infections) should be treated as early as possible to minimize areas of inflammation and subsequent scarring. Patients who have acne keloidalis nuchae should avoid shaving in the neck region, and the posterior hair should only be trimmed with scissors and trimmed no shorter than 1/8 inch.

Laser Therapy for Keloids and Hypertrophic Scars, continued

Several treatment options are available for keloids that are painful or cosmetically disfiguring. Combinations of these therapies are also effective. Patients should be advised, however, that recurrences are possible despite therapy. The earlier keloids are treated, the more likely it is that they will respond to therapy.

Intralesional corticosteroids are first-line therapy for most keloids. A systematic review found that up to 70% of patients respond to intralesional corticosteroid injection with flattening of keloids, although the recurrence rate is high in some studies (up to 50% at 5 years). Lipoatrophy may occur if the injections are done below the scar rather than in the scar. Injections can be repeated at monthly intervals, increasing the concentration of triamcinolone by 10 mg/mL on non-facial lesions until the lesion softens and flattens, then decreasing the frequency and strength of injections. Doses should not exceed 40 mg of the drug per visit; atrophy and hypopigmentation may occur at higher doses. Surgical excision is recommended if there is no response after four injections.

Silicone gel sheeting is effective in established keloids for reducing associated symptoms (e.g., pain and itching), but is most useful for preventing and managing evolving keloids in new sites of injury. In one study, for example, silicone gel sheeting was placed over evolving scars in 20 patients, with the dressing worn for at least 12 hours per day. Lesions improved during the treatment period in 85% of cases. The mechanism by which silicone gel sheeting exerts an anti-scarring effect is unknown but may be related to generation of static electricity.

Silicone gel sheeting and silicone gel are available by prescription and over-the-counter. The sheeting is clear and sticky and should be cut to fit the size of the keloid. The sheeting is placed on top of the keloid, taped into place, and left on for 12−24 hours per day. The sheet is washed daily and replaced every 10 to 14 days. Effectiveness is judged after 2−6 months of therapy.

Pressure therapy is usually performed with pressure garments, bandages, or special devices for certain locations such as the ear. A type of pressure earrings for earlobe keloids called Zimmer splints can be molded to the appropriate size and cosmetically altered to appear as earrings. Other devices using magnets with or without silicone sheeting have also been used as post-surgery adjuvant therapy for ear keloids.

The mechanism of action of pressure may involve the reduction of oxygen tension in the wound through the occlusion of small blood vessels, resulting in a decreased fibroblast proliferation and collagen synthesis. However, the optimal amount of pressure is difficult to determine. It should exceed the inherent capillary pressure without diminishing the peripheral blood circulation (20 to 30 mmHg). In one study, the applied pressure was 35 mmHg, which was estimated using a digital manometer.

The evidence to support the use of pressure therapy is limited. A 2009 meta-analysis of six high quality randomized trials including 316 burn patients did not demonstrate a difference in the global scar assessment between patients treated with pressure garments and untreated patients. Observational studies of patients with ear keloids have shown that custom-made pressure devices may be beneficial to reduce the risk of recurrence after surgical excision.

Surgical excision of hypertrophic scars and keloids may be indicated if conservative therapies alone are unsuccessful or unlikely to result in significant improvement. Surgical excision of keloids is associated with recurrence rates of up to 100 percent. The combination of surgery with adjunctive perioperative therapies can significantly lower the risk of recurrence. Surgical excision combined with preoperative, intraoperative, and postoperative intralesional injection triamcinolone acetonide has been reported in several small, uncontrolled studies using various dosages, schedules and concentrations of the drug.

In one study, 80 patients with keloids of one- to four-year duration underwent surgical excision followed by a single injection of 5-FU and botulinum toxin eight days post-surgery. Recurrence occurred in three (4 percent) patients after a follow-up time of 17 to 24 months.

Surgical excision followed by immediate freezing of the open wound was performed in one study of 66 patients with 97 large ear keloids. After a median follow-up time of 12 months, 36 percent of lesions recurred and required further treatment.

A few small observational studies have reported that postoperative use of imiquimod with daily or alternate day applications may reduce the rate of recurrence of keloids. However, other studies have provided conflicting results.

Laser Therapy for Keloids and Hypertrophic Scars, continued

Several studies have found radiation therapy to be highly effective in reducing keloid recurrence when administered immediately after surgical excision. A variety of techniques, doses, and schedules of radiation have been used in the treatment of keloids. These include megavoltage external beam radiation therapy, lower energy external radiation sources (radiographs, Co-60), electron beam, and various brachytherapy techniques. Reviews of the literature have found that the effectiveness in preventing recurrence is related to the biologically effective dose (BED) and is influenced by the site of the keloid. As an example, one report found that recurrence of keloids in the earlobe could be prevented in 90 percent of cases with a dose of approximately 16 Gy, given in three fractions using electron beam techniques. A second review reached a similar conclusion, with a BED of about 30 Gy reducing the recurrence rate to < 10 percent.

Concerns regarding the potential long-term risks associated with the use of radiation therapy limit its utilization for these lesions. Several cases of malignancy that may have been associated with radiation therapy for keloids have been reported. Although causation cannot be confirmed in these cases, caution should still be used when prescribing adjuvant radiation therapy for keloids, particularly when treating younger patients.

Radiation therapy may occasionally be indicated for lesions that are not amenable to resection.

Cryosurgery is most useful in combination with other treatments for keloids, although up to 50% of patients may respond to cryotherapy alone. The major side effect is permanent hypopigmentation, limiting its use in patients with darker skin. A 10−30 second freeze-thaw cycle is used and can be repeated up to three times per treatment session. Therapy is repeated once per month until response occurs.

Interferon alfa injections may reduce recurrence rates postoperatively. However, all currently available studies of interferon therapy suffer from methodologic problems, making an evidence-based recommendation regarding its use difficult.

Billing/Coding Information

CPT CODES

11900	Injection, intralesional; up to and including seven lesions
11901	Injection, intralesional; more than 7 lesions
17000	Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (e.g., actinic keratoses); first lesion
17003	; second through 14 lesions, each (List separately in addition to code for first lesion)
17004	; 15 or more lesions
17106	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); less than 10 sq cm
17107	; 10.0 - 50.0 sq cm
17108	; over 50.0 sq cm

HCPCS CODES

J3301	Injection, triamcinolone acetonide, not otherwise specified, 10 mg
J3302	Injection, triamcinolone diacetate, per 5 mg
J9040	Injection, bleomycin sulfate, 15 units

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Laser Therapy for Keloids and Hypertrophic Scars, continued

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Revision History

Revision Date	Summary of Changes
11/6/23	For Commercial Plan Policy, modified first-line and second-line algorithms in criteria, as follows: "1. First-Line Therapy: A 3-month trial of steroid tape/plaster, or silicone gel sheeting/silastic sheeting, or other occlusive dressings and/or pressure therapy. 2. Second-Line Therapy: A 3-month trial of at least 3 separate injections of intralesional steroids or fluorouracil, given at monthly intervals, if not previously done."
3/20/24	Modified title of policy, and for Commercial Plan Policy, updated requirements for failure of conservative therapy and added coverage criteria for superficial radiation therapy of keloids.

Laser Therapy for Keloids and Hypertrophic Scars, continued

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The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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Select Health

MEDICAL POLICY

PULSED DYE LASER TREATMENT FOR DERMATOLOGICAL CONDITIONS

Policy # 168

Implementation Date: 7/98

Review Dates: 1/4/00, 12/25/00, 2/27/01, 6/5/02, 10/23/03, 11/18/04, 11/19/05, 12/21/06, 12/20/07, 12/18/08, 12/19/09, 10/21/10, 10/13/11, 11/29/12, 10/24/13, 10/23/14, 10/15/15, 10/20/16, 10/19/17, 10/1/18, 10/9/19, 10/10/20, 10/29/21, 9/13/22, 11/16/23, 10/3/24

Revision Dates: 10/2/17, 12/11/18, 10/24/19, 11/5/21, 6/1/22, 11/20/23, 10/17/24

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Port-wine birthmarks (PWB), are a congenital malformation, typically present as a well-demarcated bright or deep red macule or patch at birth (although some birthmarks are lighter in color when they initially present.) There are also acquired PWBs that have been described in adults. As patients with PWBs age, the capillary (blood vessel) malformation grows commensurately. The abnormal blood vessels within the PWB become progressively more dilated in size which results in the lesion becoming dark purple and elevated in some instances. Nodules and hypertrophy may develop in the soft tissue underlying the PWB. Nodules may continue to grow and begin to bleed easily if traumatized.

Common areas for PWB to appear are on the face, over the areas of the first and second trigeminal nerves, and the eyes or mouth. Also, it is not uncommon to see a birthmark overlying an arteriovenous, arterial or venous malformation. PWBs in these locations require the physician to look beyond the skin for many underlying problems, including but not limited to, leptomeningeal/brain and ocular anomalies. PWB in the absence of central nervous system involvement still have the distinction of persisting into adult life, disfiguring associated areas (being psychologically distressing), bleeding, ulcerating, becoming a source of infection, and leading to systemic abnormalities such as glaucoma.

Treatment of PWB in the macular/patch stages will prevent the development of the hypertrophic component of the lesion. Laser treatment of PWB diminishes the existing blood vessels making them smaller and fewer in number. Therefore, the progression of these lesions to a more advanced size is less likely to occur. Early and aggressive treatment may permit shorter and fewer treatment sessions. Treatment in children younger than 6 months of age has also been shown to be safe and effective.

Pulsed dye laser treatment has been shown to be beneficial for other vascular lesions not limited to rosacea-related papules and pustules, and skin sensitivity that has failed other treatments.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers pulsed dye laser treatment *in limited circumstances*.

A. For removal of port-wine birthmarks, <u>one</u> of the following criteria must be met:
   1. Location on the genitals

Pulsed Dye Laser Treatment of Congenital Hemangiomas and Rosacea, continued

2. Location on the face
3. Any port-wine birthmark area that compromises vital structures, that is symptomatic (e.g., crossing joints or other vital areas where mobility/function would be impaired without treatment, bleeding, painful, ulcerated, prior infection, or pedunculated), or when there is documented evidence of physical functional impairment

B. **Select Health covers pulsed dye laser treatment of warts, hemangiomas, or pyogenic granulomas,** if they are symptomatic or causing a functional impairment, or if the member has failed 6 to 12 months of standard therapy.

Examples of standard therapy, include:

1) For warts, attempts at cryotherapy, salicylic acid, and toxic agents have failed.

2) For hemangiomas, topical beta blocker therapy has failed.

3) For pyogenic granulomas, surgical removal, if possible.

C. **Select Health does NOT cover pulsed dye laser treatment of port-wine birthmarks for cosmetic or psychological reasons.** Use for cosmetic or psychological reasons falls under the plan's cosmetic exclusion of coverage.

D. **Select Health will cover pulsed dye laser treatment for symptomatic rosacea (e.g., skin sensitivity or papules/pustules)** if the patient has failed extensive conservative therapy* for this condition.

*Trial of at least 3 different medications (topical or oral) in a 12-month period, with documentation showing that symptoms persisted despite consistent use with each medication.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

The pulsed dye laser delivers energy at a wavelength and duration that has been optimized for the selective treatment of vascular lesions. It has been used in the treatment of warts, port-wine birthmarks, hemangiomas, hypertrophic scars, and telangiectasias. Pulsed dye lasers have been used as an alternative to surgical excision or carbon dioxide lasers for many conditions.

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

Pulsed Dye Laser Treatment of Congenital Hemangiomas and Rosacea, continued

been shown to be effective in treating glomangiomas in the face and neck, as surgical excision may not be practical in these cosmetically sensitive areas. The pulsed dye laser has also shown to be effective in removing pyogenic granulomas in cosmetically sensitive areas of the face and neck.

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

17106	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); less than 10 sq cm
17107	; 10.0 to 50.0 sq cm
17108	; over 50.0 sq cm
96999	Unlisted special dermatological service or procedure

HCPCS CODES

No specific codes identified

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Pulsed Dye Laser Treatment of Congenital Hemangiomas and Rosacea, continued

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Revision History

Revision Date	Summary of Changes
11/20/23	For Commercial Plan Policy, modified requirements concerning failure of standard therapies.
10/17/24	Modified title of policy (was previously titled, "Pulsed Dye Laser Treatment of Congenital Hemangiomas and Rosacea"); and for Commercial Plan Policy, updated terminology from port-wine stains (PWS) to port-wine birthmarks (PWB) to align with current clinical standards.

Select Health

Select Health

MEDICAL POLICY

MONOCHROMATIC PHOTOTHERAPY (ANODYNE THERAPY)

Policy # 151
Implementation Date:8/15/03
Review Dates: 6/24/04, 5/20/05, 5/3/06, 5/17/07, 4/24/08, 4/23/09, 4/22/10, 9/15/11, 11/29/12, 10/24/13, 10/23/14, 10/15/15, 10/20/16, 10/19/17, 10/3/18, 10/15/19, 10/14/20, 11/28/21, 9/15/22, 10/17/23, 10/29/24
Revision Dates:

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

The Anodyne Therapy System (developed by Integrated Systems Physiology Inc.) delivers low-level infrared (890 nm) therapy directly to the skin of the affected tissue by an array of 60 super-luminous gallium aluminum arseinide diodes located on a flexible pad, 3 cm by 7.5 cm (22.5 cm^2). The average energy emitted from the diodes is 9 milliwatts per square centimeter. The density of the photo energy emitted per pad during a 30-minute treatment is 43.2 Joules/cm.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover monochromatic photo/light therapy for any indication. The quality peer-reviewed medical literature has failed to demonstrate this therapy to be effective for any clinical indication; this meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Diabetes mellitus affects over 16 million people in the United States, and nearly 30% of all diabetics develop neuropathy, a disorder that often causes progressive debilitation. Diabetic neuropathy is thought to arise from glycation of neural tissue during episodes of hyperglycemia and results in pain, loss of sensation, and muscle weakness. Loss of sensation can predispose patients to ulcerations of the feet since they cannot feel damaging pressure on or abrading of their skin. Neuropathy appears to further

contribute to ulceration by inhibiting normal vasodilation and increasing focal hypoxia in the ankle, foot, or toes. Another damaging process is that, in diabetic patients, local tissue stresses tend to result in thrombosis and necrosis rather than the more benign inflammatory response that occurs in nondiabetic patients. Since hyperglycemia plays a role in the development of neuropathy, diabetics with neuropathy are urged to maintain glycemic control as fully as possible with diet and insulin injection. Neuropathic pain may respond to anesthetics, antidepressants, analgesics, and certain other medications, whereas muscle weakness may be improved by physical therapy and exercise. In many cases, ulcerations of the lower extremities can also be prevented if patients follow a rigorous foot and skin care program.

Although the standard therapies for diabetic neuropathy are effective for some patients, many diabetics receive little benefit from treatment. According to one estimate, treatments for neuropathy, foot ulcers, and amputation for failed ulcer treatment account for half of all diabetic care costs in the United States. Monochromatic phototherapy or monochromatic near-infrared photo energy (MIRE) treatment has been studied as a way to reverse neuropathic damage by irradiation of affected areas with monochromatic infrared light. Proponents of this therapy suggest that monochromatic photo-therapy with 890 nm light may stimulate nitric oxide release, cause local vasodilation, improve circulation, and heal damaged nerves. Monochromatic phototherapy is administered in an office or clinic setting by a variety of healthcare professionals, including orthopedists, podiatrists, physiatrists, physical therapists, and chiropractors.

In April 2008, Hayes Directory re-reviewed this technology. Results of the uncontrolled and observational trials suggested that low level light therapy (LLLT) may lower the incidence and speed healing of diabetic ulcers and reduce the incidence of falls. However, 3 randomized, placebo-controlled trials failed to provide evidence that LLLT has a positive effect on overall neuropathy-specific disability. Although there is some evidence from observational and uncontrolled studies that LLLT may improve sensation in patients with peripheral neuropathy, randomized, placebo-controlled trials failed to confirm these findings. There was limited evidence from one randomized, placebo-controlled trial that LLLT in laser form may provide modest but transient pain relief, however, another placebo-controlled trial of the ATS did not report an effect on pain. There was very weak evidence that LLLT reduces the incidence of diabetic ulcers and limited evidence of a short-term reduction in falls, but these effects were not tested in randomized trials. Therefore, a Hayes Rating of 'D' is assigned to the use of LLLT for peripheral neuropathy. This rating is based on contradictory or negative evidence for most outcomes and only very weak evidence of an impact on incidence of falls and foot ulcers.

Billing/Coding Information

CPT CODES

0552T	Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional
97026	Application of a modality to one or more areas; infrared
97037	Application of a modality to 1 or more areas; low-level laser therapy (ie, nonthermal and non-ablative) for post-operative pain reduction
97039	Unlisted modality (specify type and time if constant attendance)

HCPCS CODES

E0221	Infrared heating pad system

Key References

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MEDICAL POLICY

PHOTODYNAMIC THERAPY FOR ACTINIC KERATOSES

Policy # 311
Implementation Date:9/30/05
Review Dates: 6/22/06, 8/23/07, 8/21/08, 8/13/09, 9/15/11, 11/29/12, 12/19/13, 12/18/14, 3/19/15, 2/11/16, 2/16/17, 2/15/18, 2/2/19, 2/17/20, 2/18/21, 1/10/22, 2/16/23, 2/23/24, 2/6/25
Revision Dates: 9/30/06

Description

Actinic Keratoses and Photodynamic Therapy: Clinical Overview

Actinic keratoses (AKs) are common precancerous skin lesions that arise due to cumulative sun exposure over time. These lesions typically present as single or multiple rough, scaly, or crusted plaques on sun-exposed areas of the skin, often emerging in early adulthood and increasing in prevalence with age. AKs range in color from pink to red, brown, or light gray, and they are often poorly marginated upon palpation. As the most prevalent premalignant skin lesions, AKs develop in approximately 60% of individuals over 40 years of age who are predisposed due to chronic ultraviolet (UV) exposure.

While most AKs can be effectively treated, they pose a risk of malignant transformation into invasive squamous cell carcinoma (SCC). The likelihood of progression in immunocompetent patients is approximately 8%, though reported rates vary between 0.025% and 16%, depending on individual risk factors. Immunocompromised patients face a significantly elevated risk of AKs evolving into SCC, necessitating more aggressive surveillance and management.

Photodynamic Therapy for Actinic Keratoses

Photodynamic therapy (PDT) is an established, non-invasive treatment for AKs that utilizes a light-activated photosensitizer to selectively target and destroy precancerous cells. The treatment process consists of two key steps:

1. Photosensitizer Application
   A topical photosensitizing agent—either 5-aminolevulinic acid (5-ALA) or methyl aminolevulinate (MAL)—is applied directly to the lesion using a specialized applicator. These agents penetrate the hyperkeratotic epidermis and are selectively metabolized within abnormal keratinocytes, leading to the intracellular accumulation of protoporphyrin IX (Pp-IX), a highly photosensitive compound.
2. Light Activation
   Following a prescribed incubation period (typically 3 to 48 hours, depending on lesion characteristics and clinical protocol), the treated area is exposed to a controlled light source. Light therapy can be delivered through noncoherent sources (e.g., blue or red light-emitting devices) or laser-based systems, with treatment duration generally lasting about 15 minutes. In the presence of oxygen, light activation of Pp-IX generates reactive oxygen species, such as singlet oxygen

Photodynamic Therapy for Actinic Keratoses, continued

and free radicals, which induce localized cytotoxic damage, leading to targeted destruction of AK cells.

Since 5-ALA and MAL do not selectively absorb into AK lesions alone, inadvertent application to adjacent photodamaged skin may result in unintended photosensitization of healthy tissue. Therefore, careful application is essential to minimize off-target effects.

Post-Treatment Considerations

Following PDT, treated AK lesions undergo an inflammatory response, typically manifesting as erythema, edema, burning sensation, and crusting, which resolve within 10 to 14 days. The healing process generally results in favorable cosmetic outcomes, making PDT a preferred choice for extensive field treatment in cosmetically sensitive areas such as the face and scalp. Depending on lesion response, additional treatment sessions may be required to achieve complete clearance.

By selectively targeting dysplastic cells while sparing surrounding tissue, PDT serves as an effective and well-tolerated option for the management of AKs, particularly for patients with multiple lesions or significant field cancerization.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health covers photodynamic therapy using either blue or red light sources for the treatment of actinic keratoses, as current evidence suggests equal or possibly slightly superior efficacy and near equivalency in cost-effectiveness to other standard treatment methods.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

Photodynamic Therapy for Actinic Keratoses: Evidence Review and Clinical Efficacy

A total of 18 studies were identified and analyzed in this review, including 12 well-designed randomized controlled trials (RCTs) comparing photodynamic therapy (PDT) using 5-aminolevulinic acid (5-ALA) or methyl aminolevulinate (MAL) to various treatment modalities:

- Placebo-Controlled Studies (5 studies)
- Comparative Studies Against Standard Therapies (3 studies)
- No-Treatment Controls (1 study)
- Alternative PDT Regimens (3 studies)

Photodynamic Therapy for Actinic Keratoses, continued

Collectively, these studies consistently conclude that PDT with either 5-ALA or MAL is an effective treatment for AKs, demonstrating superior cosmetic outcomes compared to other standard therapies.

Efficacy of PDT in Randomized Controlled Trials

In a double-blind, placebo-controlled study by Dragieva et al., 17 patients (120 AKs) underwent treatment with two consecutive MAL applications. Two AKs per patient were randomly selected for treatment, while others received placebo cream. After 16 weeks, the treated areas showed complete clearance in 13 patients (76%) and partial clearance in 3 patients (18%), whereas none of the placebo-treated lesions improved.

Similarly, in a randomized, double-blind study by Pariser et al., 80 patients were assigned to either MAL-PDT with red light therapy or placebo. After 3 months, 89% of PDT-treated lesions resolved completely compared to 38% in the placebo group (Pariser et al., 2003).

A more recent study by Gold et al. involved 16 patients who received a single dose of ALA with pulsed light therapyon one side of the face, while the opposite side received pulsed light alone. After 3 months, 78% of AK lesions treated with ALA-PDT had fully resolved, compared to 53.6% of untreated lesions (Gold et al., 2020).

Comparative Studies Against Standard Treatments

Fewer studies have directly compared PDT with other standard AK therapies, but available data suggest similar or superior efficacy:

- Szeimies et al. (2004) randomized 193 patients (699 AKs) to either cryotherapy with liquid nitrogen spray or MAL-PDT with red light therapy. After 3 months, lesion clearance rates were comparable (69% for PDT vs. 75% for cryotherapy).
- Freeman et al. (2003) studied 204 patients, assigning them to cryotherapy (1 session), MAL-PDT (2 sessions), or placebo PDT. After 3 months, 91% of AKs treated with PDT resolved, compared with 68% treated with cryotherapy and only 30% with placebo PDT.
- Smith et al. (2019) compared ALA-PDT (with either blue light or laser light) to topical 5-fluorouracil (5-FU). Blue light PDT was as effective as 5-FU and superior to laser light therapy, with better patient tolerability than 5-FU.

Long-Term Efficacy of PDT for AKs

Two studies assessed the durability of PDT response over a 12-month period:

- Wulf et al. (2006) conducted a study in 27 patients, randomly assigning them to red light therapy with MAL on one skin area, while another area remained untreated. After 12 months, 62% of treated lesions remained AK-free, compared to 35% of untreated lesions. Additionally, the mean time to new AK development was significantly longer in treated areas (9.6 months vs. 6.8 months in untreated areas).
- Gilbert et al. (2022) conducted a prospective trial where 15 patients received topical 5-FU for 5 days, followed by ALA-PDT on day six. After 12 months, 90% of treated AKs remained resolved, though the additive effect of 5-FU and PDT complicates interpretation of these results.

Cost-Effectiveness and Considerations

A December 2004 M-Tech review acknowledged that PDT achieves similar efficacy to blue light therapy and other standard AK treatments. However, concerns regarding long-term cost-effectiveness persist due to higher treatment costs and a lack of direct comparative studies on economic benefits. No robust cost-effectiveness analyses for PDT have been published since this report.

Photodynamic Therapy for Actinic Keratoses, continued

Recent studies highlight additional unresolved issues:

1. Adherence and Cosmetic Benefits
   PDT is often promoted as a more convenient and cosmetically favorable option compared to cryotherapy, 5-FU, or surgical excision. However, despite high patient satisfaction rates, no current literature provides direct evidence that PDT leads to higher adherence rates compared to other therapies (Braathen et al., 2021).
2. High Spontaneous Clearance Rates
   Several studies report that untreated AKs can spontaneously resolve in 35–53.6% of cases (Dragieva et al., 2004; Pariser et al., 2003; Wulf et al., 2006). This raises concerns about potential overtreatment and whether all AKs require intervention to prevent SCC progression. Further research is necessary to identify which AKs are most likely to progress to SCC and which may regress without intervention.

Conclusion

Current evidence supports PDT as an effective treatment for AKs, offering comparable or superior efficacy to standard therapies with better cosmetic outcomes and patient satisfaction. However, cost-effectiveness, optimal treatment regimens, and adherence benefits remain areas requiring further research. Additionally, more studies are needed to differentiate AKs that require treatment from those that will regress spontaneously, thereby refining clinical decision-making and ensuring judicious use of PDT.

Billing/Coding Information
Covered: For the conditions outlined above

CPT CODES

96567	Photodynamic therapy by external application of light to destroy premalignant and/or malignant lesions of the skin and adjacent mucosa (e.g., lip) by activation of photosensitive drug(s), each phototherapy exposure session

HCPCS CODES

J7308	Aminolevulinic acid HCl for topical administration 20%, single unit dosage form (354 mg)

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Members may contact Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Coverage Policy may call Select Health Provider Relations at (801) 442-3692.

Photodynamic Therapy for Actinic Keratoses, continued

Select Health

MEDICAL POLICY

PHOTOTHERAPIES FOR THE TREATMENT OF SKIN CONDITIONS

Policy # 351
Implementation Date:5/14/07
Review Dates: 4/24/08, 4/23/09, 4/22/10, 5/21/11, 11/29/12, 12/19/13, 12/18/14, 12/10/15, 12/15/16, 12/21/17, 11/27/18, 12/18/19, 12/17/20, 12/14/21, 1/13/23, 12/22/23, 11/29/24
Revision Dates: 11/11/11, 10/24/16, 5/26/17, 1/14/19, 5/11/20, 5/3/21, 4/22/22, 12/12/22, 2/17/23, 4/16/24, 12/12/24, 5/8/25

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Approximately 1% of the population in North America is affected with psoriasis. Even when skin involvement is not severe, psoriasis affects the general health of patients with the disease in many ways not limited to lower quality of life, depression, anxiety, cardiovascular disease, sleep apnea, and arthritis, among others. Most patients with skin-limited and systemic psoriatic disease are treated in the outpatient setting. The severity of psoriasis is determined by the percentage of total affected body surface area (BSA). One percent of a body surface area roughly approximates the anterior hand including the fingers. Mild psoriasis involves < 3% BSA, moderate psoriasis involves 3%–10% BSA, and severe disease is considered, if more than 10% BSA is affected. Severe disease is also considered if the hands, feet, or scalp are involved.

Phototherapy is generally used on patients with moderate-to-severe psoriasis who have not responded to more conservative therapies. Phototherapies include but are not limited broadband UV-B, PUVA, narrowband UV-B, and laser therapies.

Broadband UV light can be either UV-A (BB-UVA) at a wavelength between 320–400 nanometers (nm) or UV-B (BB-UVB) at a wavelength between 290–320 nm; with the latter considered the standard broadband range. Multiple sessions (commonly 3x/week) over 3 or more months are often required to produce lesion-clearing. While supraerythemogenic doses of UVA and UVB result in faster clearing of the lesions, the surrounding normal skin cannot tolerate such high doses and predisposes patients to dermatoheliosis and risk of skin malignancies.

An alternative to office-based phototherapy is the use of a home ultraviolet B (UVB) phototherapy unit prescribed by the treating clinician. Like phototherapy in a clinic, it requires a consistent treatment schedule. Home phototherapy units that are equipped with electronic controls that allow only a prescribed number of treatments are available and may help to mitigate clinician concerns.

Narrowband UVB (311 nm) is an alternative to standard broadband (290–320 nm) UVB in the treatment of psoriasis. Suberythemogenic doses of narrowband UVB have been shown in small studies to be more effective than broadband UVB in clearing plaque psoriasis. Apoptosis of T cells is also more common with 311 nm than with broadband UVB. This is important in the treatment of many inflammatory skin conditions.

Photochemotherapy (PUVA) involves treatment with either oral or bath psoralen, followed by ultraviolet A (UVA) radiation (320–400 nm). This treatment is an alternative to UVB therapy and is frequently used when UVB fails. UVA penetrates deeper into the dermis than UVB and does not have the latter's potential for burning the skin. With oral PUVA, patients ingest the photosensitizing drug, 8-methoxypsoralen, followed within 2 hours by exposure to UVA; this sequence is performed 3 times weekly in increasing doses until remission, then twice or once weekly as a maintenance dose. With bath PUVA, the psoralen

capsules are dissolved in water, and affected skin (hands, feet, or total body) is soaked for 15–30 minutes prior to UVA exposure.

Laser therapy works by producing intense beams of virtually non-divergent light. Xenon-chloride (XeCl) laser therapy, as delivered in a handheld device, has been used principally for patients with localized disease, involving less than 10% of the body. These patients are generally not considered candidates for other phototherapies, due to the risks of exposing the entire body to UV light. These patients are typically treated with topical therapies. Therefore, the safety and effectiveness of XeCl phototherapy must be compared to that of topical preparations. Relevant outcomes include percentage of lesions healed, time to healing, durability of healing, patient compliance with therapy (laser therapy requires multiple office visits), and the long-term effects of therapy. The side effect of greatest concern is the carcinogenic potential of UVB light exposure, although this risk may be minimized with a handheld device that spares normal skin.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

A. Select Health covers office-based PUVA, narrowband UVB, broadband UVB, and excimer laser (308 nm)/excimer light (308 nm)/targeted NB-UVB light (311−313 nm) phototherapies for the treatment of psoriasis and mycosis fungoides.

B. Select Health covers office-based PUVA, narrowband UVB, and broadband UVB phototherapies for the treatment of atopic dermatitis, lichen planus, chronic idiopathic urticaria, morphea, polymorphous light eruption, and other related skin conditions, when the member has failed at least 3 months of aggressive standard therapy in the last 2 years, for any of the following therapies: topical therapy, oral immunosuppressants, or topical and/or oral steroids.

C. Select Health covers home phototherapy (narrowband UVB) for the treatment of psoriasis and other approved skin conditions in *limited* circumstances when the below criteria are met.

Criteria for coverage (Must meet ALL):

1. Patient has one of the following diagnoses:
   a) Severe psoriasis (defined as psoriasis involving 10% BSA) refractory to topical therapy or nonbiologic systemic therapy, or
   b) Cutaneous T-cell lymphoma (CTCL)/mycosis fungoides, or
   c) Any of the skin conditions listed above with involvement of the palms or soles, also refractory to topical or nonbiologic medical therapy;

   AND
2. Patient requires UVB light treatments at least 2 times per week; and
3. Treatment has been prescribed by a dermatologist; and
4. a) Provider has documented member as having demonstrated measurable improvement with initial treatment in the provider's office after a minimum of 16 visits occurring within a 60-day period; or

   b) If in-office therapy is not available, then rent-to-purchase UVB therapy will be available if the member has demonstrated measurable improvement after a minimum of 16 therapies within the 60-day period at home.

D. Contraindications to UVB Phototherapy:

Absolute Contraindications:
1. Xeroderma pigmentosum
2. Lupus erythematosus

Phototherapies for the Treatment of Skin Conditions, continued

Relative Contraindications:

1. History of photosensitivity diseases (e.g., chronic actinic dermatitis, solar urticaria)
2. History of melanoma
3. History of nonmelanoma skin cancer
4. History of treatment with arsenic or ionizing radiation because of the increased risk for skin cancer
5. Immunosuppression for organ transplant patients

Select Health does not cover any form of phototherapy for vitiligo; this is considered cosmetic.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Published literature clearly suggests that PUVA and broadband UV-B and narrowband UV-B phototherapies are considered standard of care in the treatment of patients with moderate-to-severe psoriasis who do not respond to more conservative therapies. Studies have shown that the optimum wavelength of UVB for the treatment of psoriasis is close to 311 nm and this has led to the development of bulbs that emit UVB radiation in a 'narrowband' at this optimum wavelength. Some research has been limited to relatively short timeframes and confounded by the numerous measures of outcomes, varying indications (e.g., severity), and treatment protocols used, and general lack of control groups. As stated by Naldi et al.: “There is an urgent need to reset the research agenda focusing on long-term comparative RCTs.” Additionally, these treatments are universally covered and supported by local and national dermatologists.

Hayes rated excimer laser therapy for plaque psoriasis in adult patients as a ‘C’ in 2022, and evidence suggests excimer laser is more effective than no treatment, and excimer laser plus certain topical medications may be more effective than medications alone. Evidence also suggests that excimer laser has similar efficacy as UVB phototherapy and PUVA. It seems clear that laser therapy is approximately as effective as UV-B phototherapy in clearing lesions and perhaps faster in doing so. What remains unknown is its safety: i.e., the risk of increasing squamous and basal cell carcinomas among these patients in the long-term, as well as its cost-effectiveness because it is an expensive device. While excimer laser therapy remains an option, especially for localized plaques, its cost and unclear long-term safety profile continue to limit its widespread use. Current literature still lacks robust comparative studies to establish it as a standard alternative to phototherapy or biologics.

A Medical Technology Assessment performed in June 2011 identified 2 systematic reviews and 6 primary literature articles concerning home UV treatment for psoriasis. Several of the studies involved direct comparison of home UVB therapy to outpatient UVB therapy. In the study by Koek et al. in 2009, the equivalent efficacy of this therapy was established. Other studies such as Nolan in 2010, and the Tayside study, identified that patients prefer home UV therapy. Nolan goes as far as to state: “Home phototherapy is a well-tolerated, efficacious, economical and patient friendly therapeutic option. Advantages of home phototherapy include improved quality of life, greater convenience, lower cost, and less time lost from

work and social activities. Dermatologists should strongly consider home phototherapy as a first-line treatment option for appropriately selected psoriasis patients." The LITE (Light Treatment Effectiveness) Study, concluded in 2023, is a landmark trial comparing the effectiveness and safety of home versus office-based narrowband UVB phototherapy for psoriasis. It found that home phototherapy is non-inferior to office treatments, with 60% of patients achieving clear or almost clear skin after consistent use (2+ sessions weekly for 12 weeks). This underscores narrowband UVB's role as an effective and equitable treatment across all skin types, with the added benefit of improving accessibility and adherence for patients, particularly those in rural or underserved areas.

Questions regarding adherence to home therapy were also addressed in several studies. This is exemplified in the study by Yentzer et al. In this study, adherence data on 22 patients using acitretin and 16 patients for adherence to UVB was collected. Mean adherence to acitretin decreased steadily during the 12-week trial, whereas mean adherence to home phototherapy remained steady at 2–3 days per week. Adherence was similar between patients who reported side effects and those who did not. Recent studies highlight the cost-effectiveness of home-based UVB therapy, especially for patients who face logistical or financial barriers to office-based treatments. The LITE study further reported that adherence to home phototherapy regimens is consistent and often higher compared to oral treatments, supporting its practical utility.

For most of the literature, the issues of concern are twofold: 1) compliance/adherence to the prescribed UV regimen, and 2) cost-effectiveness of home UV as it compares to either outpatient treatment at a clinic or treatment with biologic agents. This is exemplified by the comments from Nolan et al. (2010).

Overall, most papers were supportive of the use of UVB home phototherapy. The Australia and New Zealand Horizon Scanning Network summarized the findings by stating: "It would appear that home-based UVB therapy is as effective as that offered to outpatients in a hospital setting. In addition, there was no difference in the number of adverse events recorded between the two groups." The recent LITE study strongly supports the inclusion of both home and office-based narrowband UVB phototherapy in insurance coverage as a standard care option for psoriasis. This aligns with its established effectiveness, patient adherence, and equivalence to other systemic therapies in real-world settings. Expanding access to home phototherapy, in particular, addresses equity issues and reduces treatment burden for many patients.

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

96900	Actinotherapy (ultraviolet light)
96910	Photochemotherapy; tar and ultraviolet B (Goeckerman treatment) or petrolatum and ultraviolet B
96912	Photochemotherapy; psoralens and ultraviolet A (PUVA)
96913	Photochemotherapy; (Goeckerman and/or PUVA) for severe photoresponsive dermatoses requiring at least four to eight hours of care under direct supervision of the physician (includes application of medication and dressings)
96999	Unlisted special dermatological service or procedure
96920	Laser treatment for inflammatory skin disease (psoriasis); total area less than 250 sq cm
96921	Laser treatment for inflammatory skin disease (psoriasis); 250 sq cm to 500 sq cm
96922	Laser treatment for inflammatory skin disease (psoriasis); over 500 sq cm

HCPCS CODES

Covered: For the conditions outlined above

A4633	Replacement bulb/lamp for ultraviolet light therapy system, each

Phototherapies for the Treatment of Skin Conditions, continued

E0691	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection; treatment area two square feet or less
E0692	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, four foot panel
E0693	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, six foot panel
E0694	Ultraviolet multidirectional light therapy system in six foot cabinet, includes bulbs/lamps, timer and eye protection

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Revision History

Revision Date	Summary of Changes
2/17/23	For Commercial Plan Policy, clarified timeframe requirement for aggressive standard therapy in criteria section #2: "SelectHealth covers office-based PUVA, narrowband UVB, and broadband UVB phototherapies for the treatment of atopic dermatitis, lichen planus, chronic idiopathic urticaria, morphea, and other related skin conditions, ***when the member has failed at least 3 months of aggressive standard therapy in the last 2 years***." Also, added phototherapy treatment for vitiligo as an exclusion: "SelectHealth does not cover any form of phototherapy for vitiligo; this is considered cosmetic."
4/16/24	For Commercial Plan Policy, clarified requirements for attempts at aggressive standard therapy: "**Select Health covers <u>office-based</u> PUVA, narrowband UVB, and broadband UVB phototherapies** for the treatment of atopic dermatitis, lichen planus, chronic idiopathic urticaria, morphea, and other related skin conditions, when the member has failed at least 3

	months of aggressive standard therapy in the last 2 years, ***for <u>any</u> of the following therapies: topical therapy, oral immunosuppressants, or topical and/or oral steroids."***
12/12/24	For Commercial Plan Policy, modified requirements for home phototherapy in criterion #C-4a/b: "4. a) Provider has documented member as having demonstrated measurable improvement with initial treatment in the provider's office after a minimum of 16 visits occurring within a 60-day period; <u>or</u> b) If in-office therapy is not available, then rent-to-purchase UVB therapy will be available if the member has demonstrated measurable improvement after a minimum of 16 therapies within the 60-day period at home.
5/8/25	For Commercial Plan Policy, added treatment of polymorphous light eruption with PUVA phototherapy as a qualifying condition for coverage when criteria are met.

Select Health

MEDICAL POLICY

RADIATION THERAPY FOR BASAL AND SQUAMOUS CELL CARCINOMA

Policy # 661
Implementation Date:8/1/23
Review Dates: 8/12/24
Revision Dates:3/20/25

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Non-melanomatous skin cancers (NMSC) encompass basal cell carcinoma (BCC) and squamous cell carcinoma (SCC). NMSCs are the most prevalent malignancies in the Caucasian population. The incidence is rising in large part due to an aging population. Related mortality is low but considerable morbidity can result. The most common anatomical sites are those with the most sun exposure: the head, neck, shoulders, and back. The majority of NMSCs are BCC, with 25% being SCC. The healthcare burden of NMSC is considerable. Radiotherapy is typically offered to patients who are not candidates for Mohs surgery or who refuse surgical treatment. Anatomical location-specific considerations include facial sites that would require complex procedures. Radiotherapy is being considered with more regularity as newer technologies have facilitated novel treatment techniques.

Several different types of radiotherapy can be used to treat (Basal Cell Carcinoma) BCC. External beam radiation therapy uses a linear accelerator to generate photons in the megavolt energy range. High-dose rate brachytherapy involves placement of a radioactive isotope into the patient within a body cavity, directly into tissue, or near the skin surface. More recently, electronic brachytherapy (EBT) and superficial radiation therapy (SRT) devices have become more commercially available, including the Axxent eBx System (Xoft, Inc), Intrabeam System (Carl Zeiss Meditec), and SRT-100 (Sensus Healthcare). Electronic brachytherapy and SRT differ from traditional brachytherapy and radiation therapy in that neither are true brachytherapy techniques. While both EBT and SRT transmit radiation by placing a probe near or onto the skin, the dose is not delivered from a radioactive isotope; thus, these are technically forms of external beam radiation not brachytherapy. Additionally, the energy used in EBT and SRT is in the kilovolt range and therefore has been deemed low energy, unlike the high energy (in the megavolt range) emitted by external beam radiation therapy.

The effectiveness of SRT for treatment of NMSCs was assessed based on measures of treatment success, including tumor control and recurrence, cosmetic outcomes, as well as rates of adverse events. Studies on EBT and SRT are limited, and it is important to consider that many are led by investigators who are affiliated with the manufacturers of the radiation devices. There is insufficient evidence to draw definitive conclusions regarding the use of SRT/EBT for treatment of BCCs or SCCs in adults. There is insufficient evidence to draw definitive conclusions regarding the use of SRT/EBT for the treatment of primary BCC in adults. Treatment success and recurrence rates were variable. There is also insufficient evidence to inform a conclusion regarding recalcitrant and recurrent BCC lesions, and BCC nodular, superficial, and sclerosing subtypes. NCCN does not recommend EBT or SRT for treatment of BCC. Per the AAD. Although adjuvant radiation has been recommended in patients with high-risk BCC, it appears that no RCT has been conducted to prove its benefit.

Radiation Therapy for Basal and Squamous Cell Carcinoma, continued

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does not cover superficial radiation therapy or electronic brachytherapy for the treatment of basal cell carcinoma, squamous cell carcinoma, and keloids. There is insufficient evidence affirming efficacy or safety of these treatments; this meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Billing/Coding Information

Not covered for the indications listed above

CPT CODES

0394T High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed

77401 Radiation treatment delivery, superficial and/or ortho voltage, per day

Key References

1. Hayes, Inc. Superficial Radiation Therapy for Treatment of Nonmelanoma Skin Cancer. Health Technology Brief. March 21, 2018.

Revision History

Revision Date	Summary of Changes
3/20/25	For Commercial Plan Policy, added treatment of keloids as an exclusion for superficial radiation therapy.

Select Health

Radiation Therapy for Basal and Squamous Cell Carcinoma, continued

Select Health