Cigna Medical Coverage Policy

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Subject **Actinic Keratosis Treatments**

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain ***standard*** *Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document* ***always supersedes*** *the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2013 Cigna*

Coverage Policy

Cigna covers the following treatments for actinic keratosis (AK) as medically necessary:

- cryotherapy
- topical medications[†]
- laser therapy
- photodynamic therapy[††] (PDT) using an appropriate light source with a topical photosensitizer for the treatment of nonhyperkeratotic AK lesions
- electrodessication and curettage or full-thickness excision when EITHER of the following criteria is met:
    - Progression to squamous cell carcinoma (SCC) is suspected.
    - There has been failure, intolerance or contraindication to treatment using conventional methods (e.g., cryotherapy, topical medication, laser therapy, and/or PDT).
- medium-depth chemical peels, deep chemical peels, or dermabrasion when BOTH of the following criteria are met:
    - There are at least 10 AK lesions or severe diffuse AK lesions present.
    - There has been failure, intolerance or contraindication to treatment using conventional methods (e.g., cryotherapy, topical medication, or electrodessication and curettage).

Cigna does not cover epidermal/superficial chemical peels or superficial dermabrasion for the treatment of actinic keratoses because it is considered cosmetic and not medically necessary.

[†]Note: Coverage of medications related to the treatment of actinic keratosis is subject to the pharmacy benefit portion of the applicable benefit plan.

[††]Note: Please refer to the Cigna Medical Coverage Policy: Photodynamic Therapy for Dermatologic and Ocular Conditions.

General Background

Actinic keratoses (AKs) are precancerous skin lesions that occur on the epidermis (outer layer of skin) and may result from long-term exposure to the sun. The condition is also commonly referred to as solar keratosis, senile keratosis, senile hyperkeratosis, keratoma senile and keratosis senilis. Microscopically, AK lesions show varying degrees of atypia and abnormal maturation. AKs are the most commonly treated type of premalignant lesion.

Although AK lesions are frequently asymptomatic, some exhibit signs and symptoms such as thickening, burning, itching or tenderness at the site. Lesions may vary in size from 3–10 mm in diameter and enlarge gradually. Actinic keratosis may present as a single lesion or multiple lesions on sun-exposed areas of the skin. The lesions are usually poorly demarcated, appearing as slightly erythematous papules or plaques in areas such as the face, balding scalp, posterior neck, upper chest and dorsal upper extremity. They often appear reddish in color with a white scale on top. The lesions may be difficult to see; they may feel scaly or crusted on palpation, and are better examined under intense lighting.

Although most AKs can be treated effectively, in a small number of cases these lesions have the potential to develop into squamous cell carcinomas after several years. The likelihood of an AK developing into a squamous cell carcinoma is estimated at 0.085% per lesion per year (Habif, 2009), although the estimated risk varies among sources. Up to 60% of squamous cell carcinomas develop from AKs and, while not usually aggressive, SCCs may eventually metastasize.

Current treatments focus on destroying the AKs, as no method can reliably predict if and when malignancy will develop. Lesions located on the lip, eye and ear typically are at high risk of developing into squamous cell carcinoma when left untreated. However, not all AKs need to be treated. An alternative approach to treatment is to observe the lesions over time and remove them if they exhibit clinical features indicating disease progression. Nonetheless, it is impossible to distinguish between an AK lesion and SCC, so it is generally recommended treatment should be aggressive to stop the progression to SCC (Berman, et al., 2006; Habif, 2009).

The method of treatment of AK is dependent upon location, type, and size of the lesion and whether it is a primary or recurrent lesion (American Cancer Society [ACS], 2010; National Cancer Institute [NCI], 2010). Conventional treatment methods include cryotherapy, topical medications, and laser therapy. Electrodessication and curettage, chemical peels, and dermabrasion are used less frequently but have proven effective. More recently, photodynamic therapy (PDT) and the topical application of the immunomodulator, Aldara (imiquimod), have been shown to improve patient outcomes. Lesion-directed therapy is recommended for solitary lesions while field-therapy is recommended for multiple lesions. Sequential therapy is also often employed (Del Rosso, 2011). Sequential therapy involves two groups of treatments: lesion-directed therapy performed prior to field therapy or topical field-therapy prior to lesion-directed therapy. The persistence of a lesion after treatment is suspicious and may warrant a biopsy or full excision of the lesion.

Treatment Options
Cryotherapy: The most effective and practical method of treating isolated AKs, cryotherapy, is used when AK lesions are either very few in number and small in size or multiple and scattered. Liquid nitrogen, applied directly, destroys the lesion. This method of treatment does not require anesthesia and causes the lesion to slough off, allowing new tissue growth.

Topical Medications: Topical treatments (e.g., medicated creams and solutions) are most often used in cases where multiple superficial AK lesions are present. The most widely used topical treatment is

5-fluorouracil (5–FU), also known as Efudex® (Valeant Pharmaceuticals International, Costa Mesa, CA). Other topical medications currently used in the treatment of multiple AK lesions include Solaraze® Gel (diclofenac sodium gel 3%) and Aldara™ (imiquimod). Solaraze combines nonsteroidal, anti-inflammatory diclofenac sodium in a 3% gel for topical use. Aldara is an immune response modifier, which, when used topically, will destroy the lesion.

Laser Therapy: Laser therapy employs high-intensity light to treat AK lesions. Various types of lasers may be used, including carbon dioxide, YAG, and pulsed lasers. The laser produces invisible, mid-infrared light that can be used to vaporize superficial cutaneous lesions, allowing resurfacing of the skin. Laser therapy is often recommended to treat AK of the lips (i.e., actinic cheilitis) and diffuse AK lesions.

Photodynamic Therapy (PDT): PDT is a therapy that involves applying a topical solution of 20% 5-aminolevulinic acid to atypical cells, then exposing them to blue light 14–18 hours later in order to photosensitize them. Irradiating the cells with light of an appropriate wavelength, such as that emitted by the BLU–U™ Blue Light Photodynamic Therapy Illuminator (DUSA Pharmaceuticals, Inc.®, Wilmington, MA), causes cell death. Methyl aminolevulinate (MAL) and 5-aminolevulinic acid (ALA) are both topical photosensitizer precursors used in combination with PDT. This therapy is indicated for the treatment of non-hyperkeratotic actinic keratosis of the face or scalp, as well as when more than 10 lesions require treatment. PDT can be used over large surface areas. PDT is not effective for the treatment of hyperkeratotic lesions.

Electrodessication and Curettage: Electrodessication and curettage, (i.e., scraping away the affected lesion with a curette), is often performed in conjunction with electrosurgery to inhibit possible bleeding. Because this method allows the tissue to be sent for pathological diagnosis, it is recommended in suspected cases of squamous cell carcinoma, in documented cases of previous resistance to treatments, and after biopsy.

Excision: Excisional removal may be indicated when prior treatments have been unsuccessful or when aggressive progression to squamous cell carcinoma is suspected. Individuals who are immunocompromised, have extremely sun-damaged skin, have had exposure to radiation or other known skin carcinogens, or have xeroderma pigmentosum, albinism, prior exposure to arsenicals or a personal history of skin cancer have been identified as having a high risk of developing squamous cell carcinoma.

Chemical Peels: According to Perkins and Sandel 2010, categories of chemical peels include superficial, medium-depth and deep. Superficial peels extend down to the stratum granulosum and papillary dermis. This type of chemical peel is recommended as an effective treatment for conditions which include but are not limited to mild photoaging, acne, and melasma. Medium-depth and deep chemical peels penetrate deeper into the dermis.

Although less frequently used than cryosurgery or curettage, medium and deep chemical peels have been proven effective in treating AK lesions. This method employs the topical application of chemicals to the skin, causing removal of layers of the epidermis and superficial dermis. These solutions damage the outer layer of skin, causing the skin to blister and peel off in a few days. The peeling off of treated skin stimulates new skin growth, usually within seven days. The most frequently used chemical peels are trichloracetic acid and Jessner's solution. They are reserved for cases where large numbers of AK lesions (more than 10) have been documented, when it is impractical to treat each lesion separately, and where there is a record of conventional methods, including cryotherapy, topical medications and electrodessication and curettage having proved unsuccessful. When used to treat other epidermal or dermal conditions, such as photo-aging, active acne vulgaris, acne scarring, wrinkles or uneven pigmentation, chemical peels are considered cosmetic and not medically necessary. Epidermal chemical peels affect the superficial layer of skin and are considered cosmetic.

Dermabrasion: Dermabrasion, also known as surgical skin planing, is a method of removing AK lesions by mechanically removing or "sanding" the skin using a rotary abrasive instrument. Dermabrasion is also often employed to treat wrinkles, acne and uneven pigmentation, although its use for these conditions is cosmetic and not medically necessary. While not used as often as other methods in the treatment of AK lesions, dermabrasion has proven effective in treating AK lesions in cases where numerous AK lesions (e.g., more than 10) have been documented or for severe diffuse AK lesions, when it is impractical to treat each lesion separately, and when conventional methods, including cryotherapy, topical medications and electrodessication and curettage have been tried unsuccessfully. Superficial dermabrasion involving the superficial layer of skin for the treatment of actinic keratoses is considered cosmetic and not medically necessary.

Literature Review
Evidence in the published scientific literature supports the effectiveness of various treatment options for AK and consist of both retrospective and prospective case series, randomized controlled trials, comparative trials and published reviews (Kaminaka, et al., 2009; Zeichner, et al., 2009; Kaufmann, et al., 2008; Kose, et al., 2008; level 2 Jorizzo, et al., 2007a; Braathen, et al., 2007; Moloney and Collins, 2007; Sherry, et al., 2007; Smith, et al., 2006; Morton, et al., 2006; Tschen, et al., 2006; Smith, et al., 2006; Lebwohl, et al., 2004; Thai, et al., 2004; Kurwa, et al., 1999; Whitheiler, et al., 1997; Lawrence, et al., 1995). Although few studies compare treatments to determine which provides the best outcomes, overall, the available therapies are proven to be safe, effective and well-tolerated.

Professional Societies/Organizations
Guidelines were issued by the National Comprehensive Cancer Network (NCCN) for basal and squamous cell skin cancers. As part of the identification and management of high risk patients the NCCN recommends aggressive treatment of AK at first development. In reference to treatments, the accepted treatment modalities include cryotherapy, topical 5-flourourical, topical imiquimod, photo-dynamic therapy, and curettage and electrodessication. Other modalities that may be considered include chemical peels (trichloracetic acid), and ablative skin resurfacing (laser, dermabrasion). Actinic keratosis that has an atypical clinical appearance or that do not respond to appropriate therapy should be biopsied for histologic evaluation" (NCCN, 2.2013).

Use Outside of the US: No relevant information found.

Summary
Evidence in the published scientific literature suggests that a number of treatment modalities for actinic keratoses (AK) are safe and effective; however, few studies compare treatments to determine which provide the best outcomes. The method of treatment selected depends on several variables and different methods of treatment may be necessary for different clinical cases. Since AKs have been classified as premalignant lesions, meaning that some lesions may progress to invasive squamous carcinoma, treatment of these lesions is considered medically necessary as it will ultimately help prevent future development of invasive squamous cell carcinoma. Modalities of treatment such as epidermal/superficial chemical peels and superficial dermabrasion are considered cosmetic and not medically necessary.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Cryotherapy/Laser Therapy/Destruction

Covered when medically necessary:

CPT®* Codes	**Description**
17000	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses); first lesion
17003	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses); second through 14 lesions, each (List separately in addition to code for first lesion)
17004	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses); 15 or more lesions
17110	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), of benign lesions other than skin tags or cutaneous vascular proliferative lesions; up to 14 lesions
17111	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery,

	surgical curettement), of benign lesions other than skin tags or cutaneous vascular proliferative lesions; 15 or more lesions

Photodynamic Therapy

Covered when medically necessary:

CPT®* Codes	Description
96567	Photodynamic therapy by external application of light to destroy premalignant and/or malignant lesions of the skin and adjacent mucosa (eg, lip) by activation of photosensitive drug(s), each phototherapy exposure session

HCPCS Codes	Description
J7308	Aminolevulinic acid HCL for topical administration, 20%, single unit dosage form (354 mg)
J7309	Methyl aminolevulinate (MAL) for topical administration, 16.8%, 1 g

Excision/Curettage

Covered when medically necessary:

CPT®* Codes	Description
11400	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 0.5 cm or less
11401	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 0.6 to 1.0 cm
11402	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 1.1 to 2.0 cm
11403	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 2.1 to 3.0 cm
11404	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 3.1 to 4.0 cm
11406	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; 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	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 0.6 to 1.0 cm
11422	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 1.1 to 2.0 cm
11423	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 2.1 to 3.0 cm
11424	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 3.1 to 4.0 cm
11426	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter over 4.0 cm
11440	Excision, other benign lesion including margins, except skin tags (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 0.5 cm or less
11441	Excision, other benign lesion including margins, except skin tags (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 0.6 to 1.0 cm
11442	Excision, other benign lesion including margins, except skin tags (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter

	1.1 to 2.0 cm
11443	Excision, other benign lesion including margins, except skin tags (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 2.1 to 3.0 cm
11444	Excision, other benign lesion including margins, except skin tags (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 3.1 to 4.0 cm
11446	Excision, other benign lesion including margins except, skin tags (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter over 4.0 cm

Dermabrasion

Covered when medically necessary:

CPT®* Codes	**Description**
15780	Dermabrasion; total face (eg, for acne scarring, fine wrinkling, rhytids, general keratosis)
15781	Dermabrasion; segmental, face
15782	Dermabrasion; regional, other than face

Superficial Dermabrasion

Cosmetic/Not Medically Necessary/Not Covered:

CPT®* Codes	**Description**
15783	Dermabrasion; superficial, any site (eg, tattoo removal)

Medium Depth/Deep Chemical Peels

Covered when medically necessary:

CPT®* Codes	**Description**
15789	Chemical peel, facial; dermal
15793	Chemical peel, nonfacial; dermal

Epidermal/Superficial Chemical Peels

Cosmetic/Not Medically Necessary/Not Covered:

CPT®* Codes	**Description**
15788	Chemical peel, facial; epidermal
15792	Chemical peel, nonfacial; epidermal

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