

Photodynamic Therapy for Oncologic and Dermatologic Conditions

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Coverage Policy Medical 77

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All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

Purpose:

This policy addresses medical necessity for Photodynamic Therapy.

Description & Definitions:

Photodynamic therapy (PDT) combines a drug (called a photosensitizer or photosensitizing agent) with a specific type of light to kill abnormal cells.

Criteria:

Photodynamic therapy (PDT) for oncologic or dermatologic conditions is considered medically necessary for individuals with **1 or more** of the following:

- Actinic Keratoses (AK)
- Cholangiocarcinoma (Bile Duct Cancer) that is inoperable
- Esophageal cancer with 1 or more of the following:
 - Esophagus is completely obstructed due to the cancer
 - Esophagus is partially obstructed due to cancer and YAG laser therapy is not an option for treatment
 - Barrett's esophagus carcinoma in situ and high grade disease in individuals who are not candidates for esophagectomy
- Lung cancer with 1 or more of the following:
 - Microinvasive endobronchial non-small cell lung cancer at an early stage, when surgery and radiotherapy are not indicated
 - Completely obstructing endobronchial non-small cell lung cancer

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- Partially obstructing endobronchial non-small cell lung cancer
- Non-melanoma skin tumor (including pre-malignant skin lesions and primary non-metastatic skin lesions)
 when used with topical photosensitizers (e.g., topical methylaminolevulinate, topical 5-fluorouracil, etc.)
 with 1 or more of the following:
 - Cutaneous lesions of Bowen disease (squamous cell carcinoma in situ) and appropriate clinical situation, as indicated by all of the following:
 - Need for additional therapy as indicated by **1 or more** of the following:
 - Multiple or large lesions
 - Sites where healing after surgical excision is a major concern (e.g. lower extremity, particularly pretibial area, penis, or larger lesion on digit)
 - Failure of conservative management, including 1 or more of the following:
 - 5-fluorouracil cream
 - Cryosurgery
 - Curettage with cautery or electrocautery
 - Electrodesiccation
 - Excisional surgery
 - Imiquimod cream
 - No history of Porphyria, cutaneous photosensitization, or photodermatitis
- Basal Cell Cancer and appropriate clinical situation, as indicated by All of the following:
 - Primary nodular or superficial lesion
 - Size, as indicated by 1 or more of the following:
 - Less than 2 cm in area of low risk for recurrence (eg, trunk and extremities)
 - Less than 1 cm in area of moderate risk for recurrence (eg, cheeks, forehead, neck, jawline, scalp, pretibial surface)
 - Surgical excision and radiotherapy are contraindicated or not desired by patient individual

Photodynamic therapies for oncologic and dermatologic conditions are considered **not medically necessary** for uses other than those listed in the clinical criteria, to include but are not limited to:

- Actinic cheilitis
- Actinic dermatitis
- Brain tumors (e.g., glioma)
- Breast Cancer
- Central serous chorioretinopathy
- Cervical intraepithelial neoplasia/cervical cancer
- Chronic ulcers (including diabetic ulcers)
- Colon Cancer
- Condyloma (genital warts)
- Darier's disease (keratosis follicularis)
- Disseminated superficial actinic porokeratosis
- Dyspigmentation
- Endodontic infections
- Extra-mammary Paget's disease (e.g., Paget's disease of the vulva)
- Gastric Cancer
- Granulomatous dermatitis
- Herpes labialis
- Hidradenitis suppurativa
- Human papilloma virus infection
- Intra-ocular choroidal metastases
- Keratitis
- Liposclerosis (lipodermatosclerosis)
- Mediastinal carcinoid tumor
- Mycosis fungoides

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- Nekam's disease (also known as keratosis lichenoides chronica)
- Onychomycosis
- Oral leucoplakia / leukoplakia
- Oral lichen planus
- Pancreatic Cancer
- Peri-implantitis
- Periodontitis
- Peritoneal carcinomatosis
- Photoaging
- Plantar wart
- Pleural mesothelioma
- Prostate Cancer
- Psoriasis
- Radiation retinopathy
- Respiratory papillomatosis
- Retinal hamartomas/tuberous sclerosis
- Rosacea
- Scarring
- Sebaceous hyperplasia
- Squamous Cell Carcinoma in the Head and Neck
- Squamous dysplasia of the oral cavity
- Superficial mycosis
- Type II diabetes mellitus
- Uveal melanoma
- Vulvar lichen sclerosus
- Wound healing

Coding:

Medically necessary with criteria:

Coding	Description
31641	Bronchoscopy (rigid or flexible), including fluoroscopic guidance, when performed; with destruction of tumor or relief of stenosis by any method other than excision (eg, laser therapy, cryotherapy)
43229	Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)
96567	Photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitive drug(s), per day.
96570	Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drug(s); first 30 minutes (List separately in addition to code for endoscopy or bronchoscopy procedures of lung and gastrointestinal tract)
96571	Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drug(s); each additional 15 minutes (List separately in addition to code for endoscopy or bronchoscopy procedures of lung and gastrointestinal tract)
96573	Photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitizing drug(s) provided by a physician or other qualified health care professional, per day

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96574	Debridement of premalignant hyperkeratotic lesion(s) (ie, targeted curettage, abrasion) followed with photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitizing drug(s) provided by a physician or other qualified health care professional,
	per day

Considered Not Medically Necessary:

Coding	Description
	None

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2021: March
- 2019: December
- 2015: April, September
- 2013: June
- 2012: January, June
- 2011: May, June, December
- 2010: July, September
- 2009: June
- 2008: June
- 2007: December
- 2004: November, December

Reviewed Dates:

- 2024: March
- 2023: March
- 2022: March
- 2020: April
- 2018: September, November
- 2017: November
- 2016: June
- 2015: June
- 2014: June
- 2010: June, August
- 2006: March
- 2005: October, November
- 2004: October
- 2003: May, November

Effective Date:

May 2002

References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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TITLE 21--FOOD AND DRUGS, CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, SUBCHAPTER J - RADIOLOGICAL HEALTH, PART 1040 -- PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS. 12.23.2023. Retrieved 2.23.24. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1040.11

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Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services* (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.

Keywords:

Photodynamic Therapy, shp medical 77, oncologic, dermatologic, Actinic Keratoses, AK, Cholangiocarcinoma, Bile Duct Cancer, Esophageal cancer, Barrett's esophagus carcinoma, lung cancer, Non-melanoma skin tumor, Bowen Disease, squamous cell carcinoma in situ, Basal Cell Cancer, cutaneous lesions, Photodynamic therapy (PDT), photoradiation therapy, phototherapy, or photochemotherapy

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