

## **The Department of Vermont Health Access Clinical Criteria**

**Subject:** Photodynamic Therapy

**Last Review:** November 17, 2022\*

**Past Revisions:** January 8, 2021, June 14, 2017, May 10, 2016, and May 4, 2015

**\*Please note: Most current content changes will be highlighted in yellow.**

### **Description of Service or Procedure**

Photodynamic therapy (PDT) is a treatment that utilizes a medication, termed a photosensitizer or photosensitizing agent, and a specific wavelength of light to destroy cancer cells. It is the interaction between the specific wavelengths of light and their accompanying photosensitizers that kills targeted cells. Due to the distinctive penetrating properties of different wavelengths of light, PDT allows medical professionals the ability to treat different areas of the body. PDT has alternative names including photoradiation therapy, phototherapy, or photochemotherapy.

The first step of PDT therapy involves injecting a photosensitizing agent into the bloodstream or placement on the epidermis, which is then absorbed throughout the body. Within 24-72 hours post injection, the majority of the photosensitizing agent has left the normal cells but remains in the cancer cells. The photosensitized cancer cells are then exposed to a specific wavelength of light, which creates a chemical reaction with oxygen that kills nearby cancer cells. Moreover, PDT has the capability to kill or shrink cancer cells in two other ways. The photosensitizing agent can damage the vascular supply in the tumor and may initiate the immune system to target the tumor cells.

Light wave penetration is limited to approximately one centimeter below the tissue surface, therefore PDT is typically used on cancer cells on or just below the epidermis or lining of internal organs and cavities. PDT effectiveness is reduced when treating large tumors due to limited light penetration, and generally is not used when the cancer cells have metastasized.

### **Disclaimer**

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertains to the member's aid category. Prior Authorization (PA) is only valid if the member is eligible for the applicable item or service on the date of service.



## **Medicaid Rule**

---

Medicaid and Health Care Administrative Rules can be found at <https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar/adopted-rules>

- 7102.2 Prior Authorization Determination
- 4.101 Medical Necessity for Covered Services
- 4.104 Medicaid Non-Covered Services

## **Coverage Position**

---

Photodynamic therapy may be covered for members:

- When photodynamic therapy is prescribed by a licensed medical provider enrolled in the Vermont Medicaid program, operating within their scope of practice as described on the Vermont Office of Professional Regulation's website\*, Statute, or rule who is knowledgeable in the use of photodynamic therapy and who provides medical care to the member AND
- When the clinical criteria below are met.

\* Vermont's Office of Professional Regulation's website: <https://sos.vermont.gov/opr/>

## **Coverage Criteria**

---

Photodynamic therapy may be covered for members for the following indications:

1. Palliative treatment of obstructing esophageal cancer
2. Palliative treatment of local recurrent esophageal cancer in patients who are not candidates for salvage esophagectomy
3. Barrett's esophagus with high-grade dysplasia in esophagus cells
4. Precancerous lesions in patients with Barrett esophagus
5. Palliative treatment of obstructing endobronchial lesions
  - a) Completely obstructing endobronchial non-small cell lung cancer when the patient is ineligible for surgery and radiation therapy; or
  - b) Early microinvasive endobronchial non-small cell lung cancer, when the patient is ineligible for surgery and radiotherapy; or
  - c) Partially obstructing endobronchial non-small cell lung cancer
6. Bile duct cancer
7. Nonresectable cholangiocarcinoma as an adjunct to stenting
8. Skin cancer:
  - a) Superficial or nodular basal cell carcinoma lesions in adults when the risk of recurrence is low; or
  - b) Refractory actinic keratosis; or
  - c) Advanced cutaneous T-cell lymphoma; or
  - d) Bowen's disease and nevoid basal cell carcinoma syndrome (NBCCS)
9. Malignant tumors- oral cavity, pharynx, the nasal cavity, and the larynx
  - a) Early oral squamous cell carcinoma
10. Ocular photodynamic therapy may be appropriate, as monotherapy, as a treatment of choroidal neovascularization that is visually threatening or visually impairing due to **any one** of the following is covered only when used in conjunction with verteporfin

- a) age-related macular degeneration (AMD); or
- b) pathologic myopia; or
- c) presumed ocular histoplasmosis; or
- d) chronic central serous chorioretinopathy; or
- e) choroidal hemangioma

11. Oral leukoplakia, oral lichen planus

Early and Periodic Screening, Diagnostic and Treatment (EPSDT): Vermont Medicaid will provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid members under age 21.

Please note, Vermont Medicaid Clinical Criteria is reviewed based on available literature, evidence-based guidelines/standards, Medicaid rule and policy, and Medicare coverage determinations that may be appropriate to incorporate when applicable.

**Type of service or procedure not covered (this list may not be all inclusive)**

Photodynamic therapy will not be covered for:

- Gastric cancer
- Squamous cell carcinoma of the head and neck
- Prostate cancer
- Colon cancer
- Breast cancer
- Non-cancer indications
- Cosmetic in nature
- Gynecologic tumors

**References**

Agostinis, P., Berg K., Cengel, K.A., Foster, T.H., Girotti, A.W, Gollnick, S.O., ... Golab, J. (2011). Photodynamic therapy of cancer: An update. *CA: A Cancer Journal for Clinicians*, 61(4), 250-281. doi:10.3322/caac.20114

American Cancer Society. (2022). *Photodynamic therapy*. Retrieved from <https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/photodynamic-therapy.html>

Bath-Hextall, F.J., Matin R.N., Wilkinson, D., & Leonardi-Bee, J. Interventions for cutaneous Bowen's disease. *Cochrane Database of Systematic Reviews* 6., article number CD007281. doi: 10.1002/14651858.CD007281.pub2

Centers for Medicare and Medicaid Services. (n.d.). *Early and Periodic Screening, Diagnostic, and Treatment*. Retrieved from: <https://www.medicaid.gov/medicaid/benefits/epsdt/index.html>

Centers for Medicare and Medicaid Services. *National Coverage Determination. Ocular photodynamic therapy (OPT) (80.2). NHIC Corp*. Effective 4/3/13. Retrieved from: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=128&ncdver=3&bc=AgAAQAAAAQAA&>

Cerrati, E.W. Nyugen, S.A., Farrar, J.D., & Lentsch E.J. (2015). The efficacy of photodynamic therapy

in the treatment of oral squamous cell carcinoma: A meta-analysis. *Ear, Nose & Throat Journal*, 94(2), 73-79. doi: 10.1177/014556131509400208

Cohen, D.K. & Lee, P.K. (2016). Photodynamic therapy for non-melanoma skin cancers. *Cancers*, 8(90). doi:10.3390/cancers8100090

Gallemore, R.P., Wallsh J., Hudson, H.L., Ho, A.C., Chace, R., & Pearlman J. (2017). Combination verteporfin photodynamic therapy ranibizumab-dexamethasone in choroidal neovascularization due to age-related macular degeneration: results of a phase II randomized trial. *Clinical Ophthalmology*, 11, 223-231. doi: 10.2147/OPHTH.S119510

Lee, T., Cheon, Y. & Shim, C. (2013). Current status of photodynamic therapy for bile duct cancer. *Clinical Endoscopy*, 46(1). Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3572349/pdf/ce-46-38.pdf>

Leslie, T., Lois, N., Christopoulou, D., Olson, J., & Forrester, J. (2005). Photodynamic therapy for inflammatory choroidal neovascularisation unresponsive to immunosuppression. *Journal of Ophthalmology*, 89, 147-150. doi: 10.1136/bjo.2004.046623

Moole, H., Tathireddy, H., Dharmapuri, S., Moole, V., Boddireddy, R., Yedama, P., Dharmapuri, S., Uppu, A., Bondalapati, N., & Duvvuri, A. (2017). Success of photodynamic therapy in palliating patients with nonresectable cholangiocarcinoma: A systematic review and meta-analysis. *World Journal of Gastroenterology*, 23(7), 1278-1288. doi: 10.3748/wjg.v23.i7.1278

National Comprehensive Cancer Network. *Basal Cell Skin Cancer (version 2.2022)*. NCCN Clinical Practice Guidelines in Oncology (NCCM Guidelines®). Retrieved from: [https://www.nccn.org/professionals/physician\\_gls/pdf/nmsc.pdf](https://www.nccn.org/professionals/physician_gls/pdf/nmsc.pdf)

National Institute for Health and Clinical Excellence (NICE) (2006). Photodynamic therapy for non-melanoma skin tumors (including premalignant and primary non metastatic skin lesions). *NICE Interventional Procedure Guidance*, 155. Retrieved from: <https://www.nice.org.uk/guidance/ipg155/resources/photodynamic-therapy-for-nonmelanoma-skin-tumours-including-premalignant-and-primary-nonmetastatic-skin-lesions-1899863281809349>

Nava, H., Allamaneni, S.S., Dougherty, T.J., Cooper, M.T., Tan, W., Wilding, G., & Henderson, B.W. (2011). Photodynamic therapy (PDT) using HPPH for the treatment of precancerous lesions associated with barrett's esophagus. *Lasers in Surgery and Medicine*, 43(7). doi:10.1002/lsm.21112

*Photodynamic therapy for age-related macular degeneration*. (2022). John Hopkins Medicine. Retrieved October 25, 2022 from: [http://www.hopkinsmedicine.org/healthlibrary/test\\_procedures/other/photodynamic\\_therapy\\_for\\_age-related\\_macular\\_degeneration\\_135,362/](http://www.hopkinsmedicine.org/healthlibrary/test_procedures/other/photodynamic_therapy_for_age-related_macular_degeneration_135,362/)

National Institutes for Health (2021, June 21). *Photodynamic therapy to treat cancer*. National Cancer Institute. <https://www.cancer.gov/about-cancer/treatment/types/surgery/photodynamic-fact-sheet>

Saltzman, J.R. (2022). Endoscopic palliation of esophageal cancer. In K.M. Robson (Ed.), *UpToDate*. Retrieved from <https://www.uptodate.com/contents/endoscopic-palliation-of-esophageal->

[cancer?search=esophageal%20cancer%20photodynamic%20therapy&source=search\\_result&selectedTitle=1~150&usage\\_type=default&display\\_rank=1](https://pubmed.ncbi.nlm.nih.gov/search/esophageal%20cancer%20photodynamic%20therapy&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1)

Shields, C.L., Dalvin, L.A., Lim, L. S. Chang, M., Udyaver, S., Mazloumi, M., Vichitvejpaisal, P., Su, G.L., Florakis, E., Mashayekhi, A., & Shields, J.A. (2020). Circumscribed choroidal hemangioma: Visual outcome in the pre-photodynamic therapy era versus photodynamic therapy era in 458 cases. *Ophthalmology Retina*, (4)1, 100-110. <https://doi.org/10.1016/j.oret.2019.08.004>

Siaudvytyte, L., Diliene, V., Miniauskiene, G., & Balciuniene, V.J. (2012). Photodynamic therapy and central serous chorioretinopathy. *Medical Hypothesis, Discovery & Innovation Ophthalmology Journal*, 1(4), 67-71. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3939727/pdf/mehdiophth-1-067.pdf>

Simone, C., Friedberg, J.S., Glatstein, E., Stevenson, J.P., Sterman, D.H., Hahn, S.M., & Cengel, K.A. (2012). Photodynamic therapy for the treatment of non-small cell lung cancer. *Journal of Thoracic Disease*, 4(1), 63-75. doi: 10.3978/j.issn.2072-1439.2011.11.05

Stájer, A., Kajári, S., Gajdács, M., Musah-Eroje, A., 3, & Baráth, Z. (2020). Utility of photodynamic therapy in dentistry: Current concepts. *Dentistry Journal*, 8(2). <https://doi.org/10.3390/dj8020043>

Uhlenhake, E. (2013). Optimal treatment of actinic keratoses. *Clinical Interventions in Aging*, 8. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3549675/pdf/cia-8-029.pdf>

Vohra F., Al-Kheraif, A.A, Qadri, T., Hassan, M.I., Ahmed, A., Warnakulasuriya, S., & Javed, F. (2014). Efficacy of photodynamic therapy in the management of oral premalignant lesions. A systematic review. *Photodiagnosis and Photodynamic Therapy*, 12(1). <http://dx.doi.org/10.1016/j.pdpdt.2014.10.001>

Wu, H., Minamide, T., & Yano, T. (2019). Role of photodynamic therapy in the treatment of esophageal cancer. *Digestive Endoscopy*, 31(5), 508-516. <https://doi.org/10.1111/den.13353>

Yonovsky, R.L., Bartenstein, D.W., Rogers, G.S., Isakoff, S.J., & Chen, S.T. (2019). Photodynamic therapy for solid tumors: A review of the literature. *Photodermatology, Photoimmunology, Photomedicine*, 35, 295-303. <https://doi.org/10.1111/phpp.12489>

*This document has been classified as public information.*