

MEDICAL POLICY

MEDICAL POLICY DETAILS	
Subject	PHOTODYNAMIC THERAPY FOR MALIGNANT DISEASE
Policy Number	8.01.06
Category	Technology Assessment
Effective Date	10/18/01
Revised Date	12/20/01, 01/16/03, 01/15/04, 10/20/04, 08/18/05, 06/15/06, 05/17/07, 05/14/08, 06/18/09, 05/27/10, 04/21/11, 04/19/12, 03/21/13, 02/20/14, 02/19/15, 02/18/16, 02/16/17, 02/15/18
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Product Disclaimer	<ul style="list-style-type: none"> • <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i> • <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i> • <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>

POLICY STATEMENT

- I. Based upon our criteria and assessment of peer-reviewed literature, photodynamic therapy (PDT) with Photofrin® has been medically proven to be effective and, therefore, is considered **medically appropriate** for the following indications:
- A. treatment of early stage non-small-cell lung cancer in patients who are ineligible for surgery and radiation therapy;
 - B. reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial lesions;
 - C. palliative treatment of obstructing esophageal cancer,
 - D. treatment of Barrett's high-grade dysplasia (HGD) in patients who:
 1. are considered at high risk for adverse outcomes (morbidity and mortality) during prophylactic esophagectomy surgery; and
 2. decide on this treatment method, based on shared decision-making with their physician and understanding the actual risks and benefits of various treatment options. A consensus regarding the optimal management of Barrett's high-grade dysplasia does not currently exist. Some suggest patients with HGD should undergo prophylactic esophagectomy (due to the number of concomitant adenocarcinomas missed) but esophagectomy is associated with significant mortality (3-12%) and morbidity (30-50%). For some patients, the risks of surgery may outweigh the potential benefits and PDT treatment with endoscopic surveillance may be the preferred strategy.
- II. Based upon our criteria and assessment of peer-reviewed literature, PDT has not been proven to be medically effective and therefore, is considered **investigational** in the treatment of other types of malignancies, including but not limited to: colon, rectal, pancreas, hepatobiliary, prostate, bladder, brain, skin, head and neck cancers, and Barrett's esophagus (other than high grade dysplasia as stated above).
- III. PDT with porfimer sodium is **contraindicated** in patients with any of the following:
- A. known bone marrow suppression;
 - B. porphyria or with known allergies to porphyrins;
 - C. existing tracheoesophageal or bronchoesophageal fistula; or
 - D. tumors eroding into a major vessel.

Refer to Medical Policy #8.01.01 Extracorporeal Photochemotherapy/Photopheresis.

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Refer to Corporate Medical Policy #8.01.11 Photodynamic Therapy for Subfoveal Choroidal Neovascularization.

Refer to Corporate Medical Policy #8.01.21 Light and Laser Therapies for Dermatological Conditions.

Refer to Medical Policy # 11.01.10 Clinical Trials.

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

POLICY GUIDELINES

- I. A second laser treatment (with NO additional Photofrin®) can be given 96-120 hours after the first injection, preceded by debridement (via endoscopy) two days after the initial light application.
- II. Patients may receive a second course of PDT (with Photofrin®) a minimum of 30 days after the initial therapy. Up to three courses of PDT (every 30 days) can be given.
- III. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.
- IV. As pathologists do not always agree about differentiating between low and high-grade dysplasia and between high-grade dysplasia and carcinoma in situ, many times high-grade Barrett's dysplasia is confirmed by two pathologists with expertise in gastrointestinal pathology.

DESCRIPTION

Photodynamic therapy (PDT) is a cancer treatment method using intravenous injection of a photosensitizing agent (porfimer sodium, Photofrin®) and exposure of tumor cells to a laser light source to cause cellular damage. The clearance of porfimer sodium occurs over a period of time (40-72 hours) in normal tissue; however tumor cells retain porfimer for a longer period. Treatment of the tumor is the result of selective retention of porfimer and selective delivery of light.

PDT with Photofrin® is a two-stage process. The first stage is the intravenous injection of Photofrin®. Illumination with 630-nm wavelength laser light constitutes the second stage of therapy. The laser treatment induces a photochemical, not a thermal, effect. The photochemical reaction results in the release of toxic, singlet oxygen that causes tumor necrosis.

PDT should not be confused with extracorporeal photopheresis, which is the treatment of certain skin malignancies through the use of ultraviolet light irradiation of the patient's blood.

RATIONALE

Photofrin® (porfimer sodium) is the only FDA approved photosensitizing agent with specific indications for use. Published studies have shown that PDT with Photofrin® improves the quality of life (e.g. relief of dysphagia, improvement in dyspnea) and relieves obstruction by reducing tumor mass for those patients with obstructing tumors of the esophagus or endobronchial tree. For those patients with microinvasive NSCLC, not amenable to surgery or radiation, which were treated with PDT, reported tumor response rates (50-84%) and disease-free survival rates (2.7-4.1 years) are favorable. Studies investigating the Nd: YAG laser and PDT found that survival rates were comparable and that PDT was technically easier to perform, more comfortable for patients, and caused fewer side effects (e.g. perforation).

An interim analysis of porfimer PDT for high-grade dysplasia in Barrett's esophagus demonstrated that patients receiving PDT and medication had an 80% chance of being cancer free, compared to a 50% chance of being cancer free for patients receiving medication only. The effectiveness of Photofrin® PDT in reducing the long-term risk of esophageal cancer has not been demonstrated. PDT does not completely eliminate Barrett's esophagus (with or without low/high-grade dysplasia), thus these patients still require intensive endoscopic surveillance and close follow-up.

Although PDT (using porfimer sodium or other photosensitizing agents) has been used in treatment of other cancers, all are either in Phase I or Phase II studies and have not yet been proven outside an investigational setting.

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- Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT Codes

Code	Description
96570	Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drugs(s); first 30 minutes (to be used in addition to endoscopy/bronchoscopy codes)
96571	each additional 15 minutes

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HCPCS Codes

Code	Description
J9600	Drug; porfimer sodium, 75 mg

ICD10 Codes

Code	Description
C15.3-C15.9	Malignant neoplasm esophagus (code range)
C34.00-C34.92	Malignant neoplasm bronchus and lung (code range)
C78.00-C78.02	Secondary malignant neoplasm of lung (code range)
C78.80-C78.89	Secondary malignant neoplasm of other and unspecified digestive organs (code range)
D00.1	Carcinoma in situ of esophagus
D02.20-D02.22	Carcinoma in situ of bronchus and lung (code range)
K22.70-K22.719	Barrett's esophagus (code range)

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*Key Article

KEY WORDS

Photofrin®, Porfimer sodium.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, Photodynamic therapy for malignant conditions is not specifically addressed in National or Regional Medicare coverage determinations or policies.