Protocol

Oncologic Applications of Photodynamic Therapy, Including Barrett's Esophagus

(80106)

Medical Benefit		**Effective Date**: 08/30/04	**Next Review Date**: 05/15
Preauthorization	No	**Review Dates**: 09/07, 09/08, 09/09, 05/10, 05/11, 05/12, 05/13, 05/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

Photodynamic therapy (PDT), also called phototherapy, photoradiation therapy, photosensitizing therapy, or photochemotherapy, is an ablative treatment consisting of administration of a photosensitizing agent and subsequent exposure of tumor cells to a light source of a specific wavelength to induce cellular damage. After administration of the photosensitizing agent, the target tissue is exposed to light using a variety of laser techniques. For example, a laser fiber may be placed through the channel of the endoscope, or a specialized modified diffuser may be placed via fluoroscopic guidance. Treatment selectivity for tumor cells occurs through selective retention of photosensitizing agent and selective delivery of light.

Background

PDT has been investigated for use in a wide variety of tumors, including cholangiocarcinoma and esophageal, prostate, bladder, lung, breast, brain (administered intraoperatively), skin, and head and neck cancers. Barrett esophagus also has been treated with PDT.

Barrett Esophagus

The esophagus normally is lined by squamous epithelium. Barrett esophagus is a condition in which normal squamous epithelium is replaced by specialized columnar-type epithelium known as intestinal metaplasia in response to irritation and injury caused by gastroesophageal reflux disease (GERD). Barrett esophagus occurs in the distal esophagus, may involve any length of esophagus, may be focal or circumferential, and is visualized on endoscopy with a different color than background squamous mucosa. Confirmation of Barrett esophagus requires biopsy of the columnar epithelium and microscopic identification of intestinal metaplasia.

Intestinal metaplasia is a precursor to esophageal adenocarcinoma, and patients with Barrett esophagus are at a 40-fold increased risk for developing this disease compared with the general population. Esophageal adenocarcinoma is thought to result from a stepwise accumulation of genetic abnormalities in the specialized epithelium, resulting in histologic phenotypic expression ranging from low-grade dysplasia to high-grade dysplasia to carcinoma. Most patients with nondysplastic Barrett esophagus do not progress beyond nondysplasia; the estimated rate of progression is 0.9% per patient per year. (1) In comparison, the rate of progression from low-grade dysplasia to either high-grade dysplasia or esophageal adenocarcinoma ranges from 0.5%-13.4% per patient per year. (2) Once high-grade dysplasia is present, the risk of developing adenocarcinoma is 2%–10% per patient per year; approximately 40% of patients with high-grade dysplasia on biopsy are found to have associated carcinoma in the resection specimen. (1)

Photodynamic Therapy

Several different photosensitizing agents have been used: porfimer sodium (Photofrin®), administered intravenously 48 hours before light exposure, and 5-aminolevulinic acid (5-ALA), administered orally four to six hours before the procedure. ALA is metabolized to protoporphyrin IX, which is preferentially taken up by the mucosa. Clearance of porfimer occurs in a variety of normal tissues over 40–72 hours, but tumor cells retain porfimer for a longer period. Laser treatment of Barrett esophagus may be enhanced by the use of balloons containing a cylindrical diffusing fiber. The balloon compresses the mucosal folds of the esophagus, thus increasing the likelihood that the entire Barrett mucosa is exposed to light. All patients who receive porfimer become photosensitive and must avoid exposure of skin and eyes to direct sunlight or bright indoor light for 30 days.

The indications of the U.S. Food and Drug Administration (FDA) label for porfimer sodium as of June 2011 are as follows (3):

Esophageal cancer

- Palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with Nd:YAG laser therapy

Endobronchial cancer

- Reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial non-small cell lung cancer (NSCLC)
- Treatment of microinvasive endobronchial NSCLC in patients for whom surgery and radiotherapy are not indicated

High-grade dysplasia in Barrett's esophagus

- Treatment of high-grade dysplasia in Barrett's esophagus patients who do not undergo esophagectomy

As of February 2014, oral 5-ALA has not received FDA approval for any indication. Topical 5-ALA used for treatment of actinic keratoses is addressed in a separate Protocol.

This Protocol addresses only the nondermatologic oncology applications of PDT and does not address its use in dermatologic applications, such as actinic keratosis and superficial basal cell cancer, or age-related macular degeneration. In addition, PDT should not be confused with extracorporeal photopheresis, which involves withdrawing blood from the patient, irradiating it with ultraviolet light, and then returning the blood to the patient. Extracorporeal photopheresis is addressed in a separate Protocol.

Related Protocols

Dermatologic Applications of Photodynamic Therapy

Endoscopic Radiofrequency Ablation or Cryoablation for Treatment of Barrett's Esophagus

Photodynamic Therapy for Choroidal Neovascularization

Policy (Formerly Corporate Medical Guideline)

One or more courses of photodynamic therapy may be considered **medically necessary** for the following oncologic applications:

- palliative treatment of obstructing esophageal cancer

- palliative treatment of obstructing endobronchial lesions
- treatment of early-stage non-small cell lung cancer in patients who are ineligible for surgery and radiation therapy
- treatment of high-grade dysplasia in Barrett's esophagus.

Other oncologic applications of photodynamic therapy are **investigational** including, but not limited to, other malignancies and Barrett's esophagus without associated high-grade dysplasia.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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