

Blue Cross Blue Shield of Massachusetts is an Independent Licenses of the Blue Cross and Blue Shield Association

Medical Policy

Oncologic Applications of Photodynamic Therapy, Including Barrett Esophagus

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Policy Number: 454

BCBSA Reference Number: 8.01.06 (For Plan internal use only)

NCD/LCD: NA

Related Policies

- Dermatologic Applications of Photodynamic Therapy, #463
- Endoscopic Radiofrequency Ablation or Cryoablation for Treatment of Barrett's Esophagus, #218
- Photodynamic Therapy for Choroidal Neovascularization, #600
- Focal Treatments for Prostate Cancer, #733

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

One or more courses of photodynamic therapy may be considered <u>MEDICALLY NECESSARY</u> 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 individuals who are ineligible for surgery and radiation therapy
- Treatment of high-grade dysplasia in Barrett esophagus
- Palliative treatment of unresectable cholangiocarcinoma when used with stenting.

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

Prior Authorization Information

Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed <u>inpatient</u>.

Outpatient

For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .
Medicare HMO Blue SM	Prior authorization is not required .
Medicare PPO Blue SM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code 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)
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)
96571	Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drug(s); each additional 15 minutes

HCPCS Codes

HCPCS	
codes:	Code Description
J9600	Porfimer sodium, 75 mg

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and HCPCS codes above if medical necessity criteria are met:

ICD-10 Diagnosis Codes

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ICD-10-CM Diagnosis codes:	Code Description	
045.0		
C15.3	Malignant neoplasm of upper third of esophagus	
C15.4	Malignant neoplasm of middle third of esophagus	
C15.5	Malignant neoplasm of lower third of esophagus	
C15.8	Malignant neoplasm of overlapping sites of esophagus	
C15.9	Malignant neoplasm of esophagus, unspecified	

C22.1 Intrahepatic bile duct carcinoma	
C24.0 Malignant neoplasm of extrahepatic bile duct	
C24.1 Malignant neoplasm of ampulla of Vater	
C24.8 Malignant neoplasm of overlapping sites of biliary tract	
C24.9 Malignant neoplasm of biliary tract, unspecified	
C34.00 Malignant neoplasm of unspecified main bronchus	
C34.01 Malignant neoplasm of right main bronchus	
C34.02 Malignant neoplasm of left main bronchus	
C34.10 Malignant neoplasm of upper lobe, unspecified bronchus or lung	
C34.11 Malignant neoplasm of upper lobe, right bronchus or lung	
C34.12 Malignant neoplasm of upper lobe, left bronchus or lung	
C34.2 Malignant neoplasm of middle lobe, bronchus or lung	
C34.30 Malignant neoplasm of lower lobe, unspecified bronchus or lung	
C34.31 Malignant neoplasm of lower lobe, right bronchus or lung	
C34.32 Malignant neoplasm of lower lobe, left bronchus or lung	
C34.80 Malignant neoplasm of overlapping sites of unspecified bronchus and lung	
C34.81 Malignant neoplasm of overlapping sites of right bronchus and lung	
C34.82 Malignant neoplasm of overlapping sites of left bronchus and lung	
C34.90 Malignant neoplasm of unspecified part of unspecified bronchus or lung	
C34.91 Malignant neoplasm of unspecified part of right bronchus or lung	
C34.92 Malignant neoplasm of unspecified part of left bronchus or lung	
C78.00 Secondary malignant neoplasm of unspecified lung	
C78.01 Secondary malignant neoplasm of right lung	
C78.02 Secondary malignant neoplasm of left lung	
C78.7 Secondary malignant neoplasm of liver and intrahepatic bile duct	
C78.80 Secondary malignant neoplasm of unspecified digestive organ	
C78.89 Secondary malignant neoplasm of other digestive organs	
D00.1 Carcinoma in situ of esophagus	
D02.20 Carcinoma in situ of unspecified bronchus and lung	
D02.21 Carcinoma in situ of right bronchus and lung	
D02.22 Carcinoma in situ of left bronchus and lung	
K22.711 Barrett's esophagus with high grade dysplasia	

Description

Photodynamic Therapy

Photodynamic therapy (PDT) has been investigated for use in a wide variety of tumors, including esophageal, lung, cholangiocarcinoma, prostate, bladder, breast, brain (administered intraoperatively), skin, and head and neck cancers. Barrett esophagus also has been treated with PDT. PDT for focal treatment of prostate cancer is discussed in policy #733

Several photosensitizing agents have been used in PDT: porfimer sodium (Photofrin®), administered intravenously 48 hours before light exposure, and 5-aminolevulinic acid, administered orally 4 to 6 hours before the procedure. Aminolevulinic acid 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 to 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.

Summary

Description

Photodynamic therapy (PDT; also called phototherapy, photoradiotherapy, photosensitizing therapy, or photochemotherapy) is an ablative treatment that uses a photosensitizing agent to expose tumor cells to a light source of a specific wavelength for the purpose of damaging the cells. 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 for tumor cells occurs through selective retention of the photosensitizing agent and the selective delivery of light.

Summary of Evidence

For individuals who have obstructing esophageal cancer who receive photodynamic therapy (PDT) as palliation, the evidence includes systematic reviews, randomized controlled trials (RCTs), and uncontrolled single-arm studies. Relevant outcomes are change in disease status, symptoms, quality of life, and treatment-related morbidity. A meta-analysis comparing PDT with neodymium-doped yttrium aluminum garnet (Nd:YAG) laser suggested that improvements in dysphagia are similar, although estimates are imprecise. Compared with the Nd:YAG laser, PDT is associated with a lower risk of perforation and a higher risk of adverse reactions to the light (e.g. photosensitivity). PDT plus argon plasma coagulation appears to prolong the time to recurrence of dysphagia as opposed to argon plasma coagulation alone. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have obstructing endobronchial lesions who receive PDT as palliation, the evidence includes RCTs and uncontrolled single-arm studies. Relevant outcomes are change in disease status, symptoms, quality of life, and treatment-related morbidity. Evidence from RCTs comparing PDT with Nd:YAG laser has generally supported reductions in symptoms using PDT similar to those using a laser. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have early-stage non-small-cell lung cancer (NSCLC) who are not candidates for surgery or radiotherapy who receive PDT, the evidence includes uncontrolled single-arm studies. Relevant outcomes are overall survival (OS), disease-specific survival, change in disease status, quality of life, and treatment-related morbidity. There are few patients with early-stage NSCLC who are not candidates for surgery or radiotherapy. While several treatment methods (eg, laser, electrocautery, cryotherapy, brachytherapy) are available for this population, studies comparing the treatment methods are not available. Case series of PDT include between 21 and 95 patients and have reported complete response rates ranging from 72% to 100%. Given the small size of this potential population and the ineligibility for standard surgical treatment or radiotherapy, it is unlikely that stronger evidence will become available. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with Barrett esophagus with high-grade dysplasia who receive PDT, the evidence includes 2 systematic reviews and 2 RCTs. Relevant outcomes are OS, disease-specific survival, change in disease status, quality of life, and treatment-related morbidity. One RCT compared PDT plus a proton pump inhibitor with a proton pump inhibitor alone and demonstrated higher response rates and lower risk of progression with cancer persisting during 5 years of follow-up for patients in the PDT plus proton inhibitor group. The results of the RCT also revealed that patients treated with PDT had significantly more complications, including a high rate of strictures. Another RCT compared PDT performed with different photosensitizers; results revealed that neither were valuable long-term treatments for dysplastic Barrett esophagus. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. For individuals who have unresectable cholangiocarcinoma who receive PDT plus stenting as palliation, the evidence includes systematic reviews, RCTs, and observational studies. Relevant outcomes are change in disease status, symptoms, quality of life, and treatment-related morbidity. Three small RCTs and several observational studies have found that PDT plus stenting is associated with the greater elimination of bile duct stenosis and improved survival benefit compared with stenting alone. One RCT comparing stenting plus chemotherapy and PDT with stenting plus chemotherapy without PDT reported longer progression-free survival, but not OS, with similar adverse event rates. Case series have suggested an improvement in the quality of life with PDT. The main complication of PDT in cholangiocarcinoma is cholangitis. Given the small size of this potential population, it is unlikely that stronger evidence will become available. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have other malignancies (eg, gynecologic, bladder, head and neck, brain, soft tissue) who receive PDT, the evidence includes controlled observational studies and uncontrolled single-arm studies. Relevant outcomes are OS, disease-specific survival, change in disease status, quality of life, and treatment-related morbidity. The published literature on PDT for these malignancies is generally comprised of small case series without comparator groups. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
9/2023	Annual policy review. Reference added. Minor editorial refinements to policy statements; intent unchanged.
9/2022	Annual policy review. Reference added. Minor editorial refinements to policy statements; intent unchanged.
8/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
9/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
9/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
9/2018	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2018	Annual policy review. New medically necessary indications described. Clarified coding information. Effective 1/1/2018.
5/2015	Annual policy review. New references added. Clarified coding language.
7/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
5/2014	Annual policy review. New references added.
1/2014	Added new CPT code 43229 and removed deleted code 43228.
6/2013	Annual policy review. New references added.
5/2013	Annual policy review. New references added.
11/2011- 4/2012	Medical policy ICD10 remediation: Formatting, editing and coding updates. No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use

Managed Care Guidelines

Indemnity/PPO Guidelines

Clinical Exception Process

Medical Technology Assessment Guidelines

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