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EVIDENCE-BASED CRITERIA  
SECTION: MEDICINE

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## ONCOLOGIC APPLICATIONS OF PHOTODYNAMIC THERAPY, INCLUDING BARRETT ESOPHAGUS

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Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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## **ONCOLOGIC APPLICATIONS OF PHOTODYNAMIC THERAPY, INCLUDING BARRETT ESOPHAGUS**

### **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.

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, as well as Barrett esophagus. The photosensitizing agent porfimer sodium (Photofrin®; Pinnacle Biologics) was approved by the U.S. Food and Drug Administration (FDA).

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### **Criteria:**

- One or more courses of photodynamic therapy are considered **medically necessary** with documentation of **ANY** of the following oncologic applications:
  1. Palliative treatment of obstructing esophageal cancer
  2. Palliative treatment of obstructing endobronchial lesions
  3. Treatment of early-stage non-small-cell lung cancer in individuals who are ineligible for surgery and radiotherapy
  4. Treatment of high-grade dysplasia in Barrett esophagus
  5. Palliative treatment of unresectable cholangiocarcinoma when used with stenting.

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- Photodynamic therapy for all other oncologic indications not previously listed or if above criteria not met is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

These indications include, *but are not limited to*:

- Barrett esophagus without associated high-grade dysplasia
- Other malignancies

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### Resources:

**Literature reviewed 09/03/24. We do not include marketing materials, poster boards and non-published literature in our review.**

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**EVIDENCE-BASED CRITERIA  
SECTION: MEDICINE**

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LAST CRITERIA REVISION DATE: 09/21/23  
ARCHIVE DATE:**

**NEXT ANNUAL REVIEW DATE: 3RD QTR 2025**

## **ONCOLOGIC APPLICATIONS OF PHOTODYNAMIC THERAPY, INCLUDING BARRETT ESOPHAGUS**

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### **History:**

| <b><u>History:</u></b> | <b><u>Date:</u></b> | <b><u>Activity:</u></b>                 |
|------------------------|---------------------|---|
| Medical Policy Panel   | 09/03/24            | Review with revisions                   |
| Medical Policy Panel   | 09/21/23            | Review with revisions                   |
| Medical Policy Panel   | 08/01/23            | Review with no revisions                |
| Medical Policy Panel   | 08/16/22            | Approved guideline (Effective 09/19/22) |

### **Policy Revisions:**

|          |          |  |
|----------|----------|--|
| 09/03/24 | Updated: | Resources section  |
| 09/21/23 | Added:   | “Insufficient evidence to support improvement of the net health outcome; or”, and “Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or” to experimental or investigational criteria. |
| 09/21/23 | Revised: | “patients” to “individuals” in medically necessary criteria; “Insufficient evidence to support improvement outside the investigational setting” from #3 to #5 in experimental or investigational criteria.   |
| 09/21/23 | Updated: | Resources section  |



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## ONCOLOGIC APPLICATIONS OF PHOTODYNAMIC THERAPY, INCLUDING BARRETT ESOPHAGUS

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Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

