

Medical Affairs Policy & Procedure

Title/Service: Photodynamic Therapy (Levulan Kerastick, methyl aminolevulinate HCl, Metvixia, porfimer, verteporfin, Visudyne, 20% delta-aminolevulinic acid HCl)

Revised	09/16/2011
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Description:

Photodynamic therapy (PDT) uses a photosensitizing drug (a drug that becomes activated by light exposure) followed by a particular type of light which activates the drug, generating a process creating a toxic form of oxygen. Abnormal, rapidly growing or cancerous cells and blood vessels take up more of the drug and retain the drug for a longer duration than normal tissues, enabling the light to focus on and destroy abnormal tissue.

Indications of Coverage:

- A. Photodynamic therapy (PDT) using verteporfin (Visudyne) for conditions of the **eye** is considered medically necessary when the documentation supports a confirmed diagnosis of one of the following:
1. Subfoveal choroidal neovascularization with current leakage due to exudative (wet) macular degeneration, pathologic myopia, or presumed ocular histoplasmosis
 2. Central serous chorioretinopathy (CSCR)
 - Initial approval is made for one injection. Subsequent treatment may be approved for treatments at three month intervals (one to four treatments, depending on chronicity) if there is ongoing leakage and documentation of continued therapeutic response. This treatment is an alternative to injections with anti-VEGF agents such as Lucentis or Avastin.
- B. Photodynamic therapy (PDT) using aminolevulinic acid or methyl aminolevulinate (Levulan Kerastick or Metvixia) for conditions of the **skin** is considered medically necessary when one of the following situations is documented:
1. Minimally to moderately thick actinic keratoses (grade 1 or 2) of the face or scalp which have failed to respond to treatment with imiquimod (Aldara), fluorouracil (Efudex), or liquid nitrogen

2. Superficial basal cell carcinoma when surgery is contraindicated
 3. Bowen's disease (superficial squamous cell carcinoma) when surgery is contraindicated
- One Levulan treatment may be allowed; if a lesion persists after eight weeks, one more treatment may be allowed. The application of the Levulan is authorized for day one, the blue light therapy on day two (or 14 to 18 hours later). Two Metvixia treatments may be allowed one week apart; the light treatment is performed the same day as the cream application.
- C. Photodynamic therapy (PDT) using porfimer (Photofrin) for non-skin pre-malignant or malignant conditions is considered medically necessary for any of the following:
1. High-grade dysplasia (carcinoma in situ) in **Barrett's esophagus** for individuals who are not candidates for esophagectomy (for example, due to severe cardiopulmonary disease)
 2. Partially obstructing **esophageal cancer** in individuals where treatment with the Nd:YAG laser is contraindicated
 3. **Esophageal cancer** tumors that completely obstruct the esophagus
 4. Early stage endobronchial **non-small cell lung cancer** (NSCLC) where surgery and radiation therapy are contraindicated (for example, due to severe cardiopulmonary disease)
 5. Completely or partially obstructing endobronchial **non-small cell lung cancer** (NSCLC)

Limitations of Coverage:

- A. Review contract and endorsements for exclusions and prior authorization or benefit requirements.
- B. If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.
- C. If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.
- D. The use of photodynamic therapy is considered investigational for any of the following conditions as there is insufficient peer-reviewed scientific literature supporting the effectiveness of photodynamic therapy for these conditions:
 - Acne
 - Hyperkeratosis (thickening of a layer of the skin)

- Psoriasis
- Photoaging
- Warts
- Subfoveal choroidal neovascularization of unknown origin
- Cholangiocarcinoma (cancer of the bile ducts)
- Prostate cancer

Documentation Required:

- Office notes
- Prescription medication use data

Rationale:

Phototherapy involves the use of certain lights in combination with a sensitizing drug that allows treatment to be concentrated on abnormal cells or blood vessels. Each sensitizing drug is activated by light of a specific wavelength, which determines how deep into the tissue the light will travel. When the light is activated, the sensitizing drug reacts with oxygen in the cell, causing cell death. This allows destruction of the abnormal cells and minimizes effects on healthy cells. Additional uses of these drugs for cancers and conditions of the skin are being studied, but the studies are not complete.

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Approved by the Medical Director