Medical Coverage Policy | Dermatologic Applications of Photodynamic Therapy

EFFECTIVE DATE: 00|00|2019
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OVERVIEW
Photodynamic therapy (PDT) refers to light activation of a photosensitizer to generate highly reactive intermediaries, which ultimately cause tissue injury and necrosis. Photosensitizing agents, administered orally or intravenously, have been used in nondermatologic applications and are being proposed for use with dermatologic conditions such as actinic keratoses and nonmelanoma skin cancers.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Commercial Products
Photodynamic therapy is medically necessary as a treatment of nonhyperkeratotic actinic keratoses of the face and scalp, superficial basal cell skin cancer only when surgery and radiation are contraindicated, and for the treatment of Bowen disease (squamous cell carcinoma in situ) only when surgery and radiation are contraindicated.

Photodynamic therapy is not medically necessary for all other dermatologic applications, including but not limited to, acne vulgaris, nonsuperficial basal cell carcinomas (BCC), hidradenitis suppurativa, and mycoses, or as a technique of skin rejuvenation, hair removal, or other cosmetic indications as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable medical and not medically necessary benefits/coverage.

BACKGROUND
Photodynamic therapy (PDT) refers to light activation of a photosensitizer to generate highly reactive intermediaries, which ultimately cause tissue injury and necrosis. Photosensitizing agents are being proposed for use with dermatologic conditions such as actinic keratoses and nonmelanoma skin cancers.

For individuals who have nonhyperkeratotic actinic keratoses on the face or scalp who receive PDT, the evidence includes randomized controlled trials (RCTs). The relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Evidence from multiple RCTs has found that PDT improves the net health outcome in patients with nonhyperkeratotic actinic keratoses on the face or scalp compared with placebo or other active interventions. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have low-risk basal cell carcinoma who receive PDT, the evidence includes RCTs and systematic reviews of RCTs. The relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Systematic reviews of RCTs have found that PDT may not be as effective as

surgery for superficial and nodular basal cell carcinoma. In the small number of trials available, PDT was more effective than placebo. The available evidence from RCTs has suggested that PDT has better cosmetic outcomes than surgery. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have squamous cell carcinoma in situ who receive PDT, the evidence includes RCTs. The relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. RCTs have found that PDT has similar or greater efficacy compared with cryotherapy and 5-fluorouracil. Additionally, adverse events and cosmetic outcomes appear to be better after PDT. Few RCTs have compared PDT with surgery or radiotherapy; as a result, conclusions cannot be drawn about PDT compared with these other standard treatments. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have nonmetastatic invasive squamous cell carcinoma who receive PDT, the evidence includes observational studies and a systematic review of observational studies. The relevant outcomes are overall survival, symptoms, change in disease status, quality of life, and treatment-related morbidity. Conclusions cannot be drawn from small, uncontrolled studies. RCTs are needed to determine the safety and efficacy of PDT for this condition. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have acne who receive PDT, the evidence includes RCTs and a systematic review. The relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The available RCTs have not consistently found significantly better outcomes with PDT compared with other interventions, and a meta-analysis did not find significantly better results with PDT vs placebo. Several trials have found that PDT is associated with high rates of adverse events leading to the cessation of treatment. Trials tended to have relatively small sample sizes and used a variety of comparison interventions. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have noncancerous dermatologic skin conditions (eg, hidradenitis suppurativa, mycoses, port wine stain) who receive PDT, the evidence includes case series, systematic reviews of uncontrolled series, and an RCT for port wine stain. The relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. RCTs are needed to determine the safety and efficacy of PDT for these conditions. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

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The following codes are considered ~~not~~ medically necessary when filed with the one of the diagnosis below:

96567 Photodynamic therapy by external application of light to destroy premalignant and/or malignant lesions of the skin and adjacent mucosa (e.g., lip) by activation of photosensitive drug(s), each phototherapy exposure session.

J7308 Aminolevulinic hydrochloric acid for topical administration, 20%, single unit dosage form (354 mg)

J7309 Methyl aminolevulinate (MAL) for topical administration, 16.8%, 1 gram

ICD10 codes:
L57.0
C44.0-C44.9
D04.0-D04.9

RELATED POLICIES

BlueCHiP for Medicare National and Local Coverage Determinations

PUBLISHED

Provider Update, June 2019

Provider Update, February 2019
Provider Update, March 2017
Provider Update, May 2016
Provider Update, May 2015

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