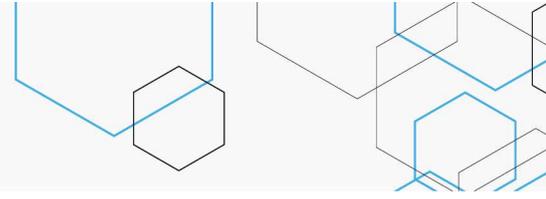


# Photodynamic Therapy for non-melanoma skin cancer



**Technology:** Photodynamic Therapy

**Indication:** Non-melanoma skin cancer lesions

**Applicant:** Optics and Photonics Research Center (CePOF) - University of São Paulo (USP)

**Background:** Non-melanoma skin cancer is the neoplasm with the highest incidence, but with low lethality and favorable prognosis when treated early. Basal cell carcinoma (BCC) accounts for 80% of cases, and it is slow growing and less aggressive. The gold standard for treatment is surgical excision of the tumor, which is a recommendation established in several international guidelines, such as in Brazil. However, its indication should be discussed when the lesion is located in some critical areas with regards to physical appearance. Some topical modalities available offer good cosmetic results and no recurrences, but some tumor characteristics, such as size, location and pathology, influence the selection of treatment. In addition, cost and patient's preference should be considered when selecting the appropriate therapy.

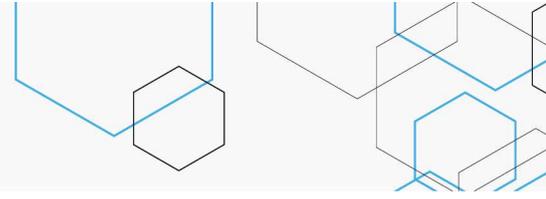
**Question:** Is photodynamic therapy effective, safe and cost-effective for the treatment of non-melanoma skin cancer when compared to surgery?

**Scientific evidence:** Photodynamic therapy (PDT) was shown to be less effective than surgery for the complete resolution of the lesion (risk ratio [RR] = 0.93; 95% confidence interval [CI] 0.89-0.98). The studies analyzed were heterogeneous regarding the risk of recurrence at 12 months, affecting the accuracy of the results and impacting on the quality of the evidence, but the results showed that patients treated with photodynamic therapy presented 12 times more chance of lesion recurrence compared with the group treated with surgery (RR 12.42; CI 2.34-66.02). A better cosmetic effect was twice as high with photodynamic therapy (odds ratio [OR] 1.87; CI 1.54-2.26) compared with the group treated with surgery.

**Economic evaluation:** Photodynamic therapy was shown to be cost-effective (dominant strategy: less costly and more effective) as far as good cosmetic outcomes are concerned, compared with surgical removal of low-risk basal cell carcinomas, in a decision model with a time horizon of up to five years. This result is obtained even when taking into consideration the impact of recurrence in the accounting of benefits. However, PDT would not be cost-effective if the cosmetic outcome is not considered in the analysis, due to its poor performance in relation to resolution and recurrence of lesions.

**Budget impact analysis:** Based on the budget impact scenarios developed, it would be necessary to increase the budget by more than BRL 3 million in one year, in order to make PDT available to all patients with superficial basal cell carcinomas. In an alternative scenario, where PDT would be restricted to superficial head and neck tumors, the incremental impact was estimated to be approximately BRL 1.1 million.

**International experience:** The National Institute for Health and Clinical Excellence (NICE) of the United Kingdom (UK) recommends photodynamic therapy for non-melanoma skin tumors (including premalignant and primary non-metastatic skin lesions). Recommendations on the use of photodynamic therapy from the Canadian Agency for Drugs and Technologies in Health (CADTH) have not been identified.



**Considerations:** The findings have demonstrated that photodynamic therapy is effective in removing lesions, with cosmetic advantages when compared with traditional surgery, but also with a higher risk of recurrence. Photodynamic therapy can be an alternative to surgical excision for low-risk superficial tumors in situations where the cosmetic outcome has a significant impact on the choice of treatments.

**Initial Recommendation:** Conitec, at its 82nd Ordinary Meeting, on October 10th, 2019, decided not to recommend the incorporation of photodynamic therapy in the scope of the Brazilian Public Health System (SUS), for patients with non-melanoma skin cancer lesions, specifically low-risk basal cell carcinoma (superficial BBCs < 2 cm diameter or nodular BBCs < 2 mm in thickness). It was considered that, despite the cosmetic benefits of photodynamic therapy, the scientific evidence presented by the applicant is not strong enough, especially regarding efficacy and safety compared to surgery.

**Public consultation:** The public consultation No. 67/2019 was held from November 25th to December 16th, 2019. A total of 1,277 contributions were received, of which 129 (10%) were technical-scientific contributions, and 1,148 (90%) were experience or opinion contributions of patients, relatives, friends or caregivers of patients, health professionals or people interested in the subject. After analyzing the contributions received in the Public Consultation No. 67/2020, the Conitec's plenary session considered that: I) despite photodynamic therapy was shown to be cost-effective (dominant strategy: less costly and more effective) as far as good cosmetic outcomes are concerned, compared with surgical removal of low-risk basal cell carcinomas, this result should not outweigh the risks associated with its poor performance in relation to the recurrence of lesions; II) the difficulty of ensuring that PDT would be used only in superficial tumors.

**Final Recommendation:** The Conitec's members present at the 85th Ordinary Meeting, on February 4th, 2020, unanimously decided not to recommend the incorporation of photodynamic therapy for the treatment of non-melanoma skin cancer lesions, specifically superficial basal cell carcinoma, as an alternative to surgery. The Deliberation Record No. 498/2020 was signed.

**Decision:** Not to incorporate Photodynamic Therapy for the treatment of non-melanoma skin cancer lesions, specifically superficial basal cell carcinoma, in the scope of SUS, according to Ordinance No. 5, published in the Official Gazette of the Federal Executive No. 44, Section 1, page 130, on March 5th, 2020.

