



November 25, 2024

Mr. Gift Tee

Director
Division of Practitioner Services
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Via email: gift.tee@cms.hhs.gov

Re: Proposed Final Rule for the 2025 Medicare Physician Fee Schedule

Dear Mr. Tee;

STRATA Skin Sciences, Inc. is the sole US manufacturer and distributor of the Excimer laser used by dermatologists to treat a variety of inflammatory skin diseases, including psoriasis and vitiligo, among other conditions. We have previously reached out to the Center for Medicare & Medicaid Services requesting a meeting to discuss the issues in the proposed and final rule for the 2025 Medicare Physician Fee Schedule that negatively impacts:

- (1) patients using the excimer laser therapy, or eligible to use it;
- (2) dermatologists who have provided these services to their patients who previously could and now cannot bill for many of the FDA cleared uses;
- (3) the adverse impact on the elderly, the poor, and people of color; and
- (4) the direct impact on physicians due to changes in coding and payment that will significantly negatively impact their bottom lines, forcing them to prescribe higher cost treatment options.

Of course these changes impact Strata's bottom line also, and we have a significant stake in the ultimate resolution of this matter.

In our request, we provided our comments to CMS on the proposed rule, background information on the excimer laser therapy and eligible patients, and citations to the many clinical studies that support the use of this technology for multiple inflammatory skin disease.

In our initial outreach to CMS to address the inequalities brought which would be the inevitable outcome of CMS' actions, we identified several CMS recommendations (now final in the latest rulemaking) that significantly affect the availability of this therapy to many patients currently receiving treatment or who might need such treatment in the future. We suggested actions that could ease the current situation for patients enrolled in Medicare, such as creation of a G code to protect Medicare beneficiaries' access to this therapy, as we work to correct the CPT codes for this service that were modified in 2024 to limit code coverage to only one of the accepted inflammatory skin conditions. We also pointed out that the data used by CMS in practice expense values (provided by the American Medical Association's Relative Value

Update Committee) were not correct as they related to the costs of the excimer laser used by physicians for these therapies.

In CMS' response to our comments and those of other impacted stakeholders, CMS raised two critical issues that we want to address in this letter.

1) **Non-Psoriasis Indications**

The first concern raised was that the clinical data submitted to CPT in 2023 was deemed insufficient to expand the code's scope to include non-psoriasis inflammatory skin diseases, despite the many years' long use of excimer lasers for these conditions by dermatologists, and previously covered by the CPT codes. STRATA was not consulted during this review and is therefore unaware of the specifics in the CPT application. CMS did not identify what studies it had used to support this position. However, we present below a robust collection of high-quality clinical studies supporting excimer laser efficacy across multiple indications, with adoption by over 4,000 U.S. dermatologists.

The CPT code descriptor changes implemented in early 2024 have disproportionately impacted patients, particularly the elderly and people of color. STRATA is actively collaborating with the CPT editorial panel to provide additional clinical evidence for excimer laser use in non-psoriasis indications.

As part of this communication, we are re-attaching a data compendium (Appendix A) of hundreds of clinical studies supporting the excimer laser's versatility. Additionally, (Appendix B) includes key studies demonstrating positive clinical outcomes for conditions like vitiligo, atopic dermatitis, leukoderma, and alopecia areata. Below is a brief summary of these studies.

a) **Vitiligo**

90+ clinical studies from across the globe support the use of excimer laser as a monotherapy and/or a conjunctive therapy for the treatment of vitiligo. Several key studies are highlighted below as an example:

- i) **Spencer et al.¹ (2002)** conducted a pilot study at Mount Sinai School of Medicine, to evaluate the 308-nm excimer laser for vitiligo treatment. This single-arm study included 18 patients with 29 vitiligo patches, featuring skin types I to VI. The treatment protocol involved three sessions per week for up to 12 treatments. Results showed 57% repigmentation after six treatments and 82% after 12, with no significant adverse events. **Patients with darker skin types (III-VI)** showed more pronounced repigmentation, with some achieving complete results, such as periocular skin repigmentation in a patient with type V after only five treatments.
- ii) **Taneja et al.² (2003)** conducted a study at Massachusetts General Hospital, Harvard Medical School, to evaluate the 308-nm excimer laser for treating localized vitiligo. This study involved 15 participants (ages 19–59, skin types II–VI) with stable vitiligo lesions **resistant to prior treatments**. Patients received twice-weekly treatments for up to 60 sessions, starting at 100 mJ/cm² with dose increments based on erythema response. Results

¹ James M. Spencer, Robert Noss, Jyotendra Ajmeri, Treatment of vitiligo with the 308-nm excimer laser: A pilot study, Journal of the American Academy of Dermatology, Volume 46, Issue 5, 2002, Pages 727-731, ISSN 0190-9622, <https://doi.org/10.1067/mjd.2002.121357>

² Taneja, A., Trehan, M. and Taylor, C.R. (2003), 308-nm excimer laser for the treatment of localized vitiligo. International Journal of Dermatology, 42: 658-662. <https://doi.org/10.1046/j.1365-4362.2003.01997.x>

- showed site-specific repigmentation with facial lesions achieved over 75% repigmentation (grade 4) in most cases. The laser was well-tolerated with no significant adverse events.
- iii) **Hadi et al.³ (2004)** conducted a prospective clinical trial at Mount Sinai School of Medicine, involving 32 patients aged 4 to 71 years with skin types I–VI and 55 vitiligo patches. The study evaluated the safety and efficacy of the 308-nm excimer laser, with patients receiving twice-weekly treatments for up to 30 sessions or until achieving 75% repigmentation. Results showed significant repigmentation in 52.8% of patches, with 71.5% on the face achieving 75% repigmentation. The treatment was well-tolerated, including in **children as young as 4 years**, with minimal adverse events.
 - iv) Expanding further, **Choi et al.⁴ (2004)** conducted a comprehensive study in Korea at Hanyang University Hospital and Choi's Dermatology Clinic, involving 69 patients with 140 vitiligo patches. Patients received treatments twice weekly with area-specific initial doses. The results revealed significant repigmentation in 72.2% of treated patches after 30 treatments, with facial areas responding best. Skin types III–IV predominated, and adverse effects, including prolonged erythema, were mild and well-tolerated.
 - v) **Al-Shobaili et al.⁵ (2015)** conducted a study at Qassim University in Saudi Arabia to evaluate the impact of 308-nm excimer laser treatment on the **quality of life (QoL) in vitiligo patients**. The study included 134 patients with 386 lesions, assessed using the Dermatology Life Quality Index (DLQI) and Visual Analogue Scale (VAS). Results showed significant improvement in five of six QoL domains, with the most notable improvements in facial and exposed areas. **Life satisfaction increased significantly, and life disturbance decreased.** The study underscores the excimer laser's ability to improve vitiligo patients' psychosocial well-being despite varied clinical outcomes.

Together, these studies showcase the excimer laser's ability to provide rapid, repigmentation for vitiligo. Its efficacy, particularly for darker skin types and specific body areas like the face and neck, positions it as a valuable therapeutic option improving the quality of life for patients (especially the ones with darker skin types) having facial involvement.

b) Atopic Dermatitis

Multiple prospective studies show the value of excimer laser as a treatment for atopic dermatitis

- i) **Baltás et al.⁶ (2006)** conducted a study at the University of Szeged, Hungary, to evaluate the efficacy of the 308-nm excimer laser for atopic dermatitis (AD). The study included 15 patients (mean age 17.3 years) with lesions on flexor surfaces, treated twice weekly for 4 weeks. Results showed significant reductions in erythema, lichenification, excoriation, and pruritus, with an 81% improvement in itching scores. Local eczema severity index decreased from a baseline mean of 8.5 to a post-treatment mean of 3.75. Quality of life went from a baseline mean of 6.57 to a post-treatment mean of 1.71. The treatment was well-tolerated

³ Hadi, S. M., Spencer, J. M., & Lebwohl, M. (2004). The Use of the 308-nm Excimer Laser in the Treatment of Vitiligo: A Pilot Study. *Journal of the American Academy of Dermatology*, 51(5), 764–768. DOI: 10.1016/j.jaad.2004.04.005

⁴ Choi, K. H., Park, K. C., Youn, S. W., & Lee, E. S. (2004). Treatment of Vitiligo with the 308-nm Xenon-Chloride Excimer Laser: Therapeutic Efficacy of the Excimer Laser in Vitiligo. *The Journal of Dermatology*, 31(4), 284–292. DOI: 10.1111/j.1346-8138.2004.tb00574.x.

⁵ Al-Shobaili HA. Treatment of Vitiligo Patients by Excimer Laser Improves Patients' Quality of Life. *Journal of Cutaneous Medicine and Surgery*. 2015;19(1):50-56. doi:10.2310/7750.2014.14002

⁶ Baltas E, Csoma Z, Bodai L, Ignacz F, et al. Treatment of atopic dermatitis with the xenon chloride excimer laser. *J Eur Acad Dermatol Venereol* 2006;20:657–60.

with no significant adverse effects, suggesting the excimer laser is a promising option for atopic dermatitis.

- ii) **Brenninkmeijer et al.⁷ (2010)** conducted a study at the University of Amsterdam that showed superior efficacy of the **308-nm excimer laser** over **clobetasol propionate 0.05% ointment** for localized atopic dermatitis (AD). In this randomized split-body trial involving 10 patients, each received excimer laser therapy on one side of the body and clobetasol ointment on the other. The excimer laser showed superior results, reducing nodules, excoriations, erythema, pruritus, and induration, with histological improvements like decreased epidermal thickness and parakeratosis. Recurrence rates were also lower with the excimer laser.

c) **Leukoderma**

Due to the low prevalence of Leukoderma, most of the studies supporting the use of excimer laser are case reports but multiple case reports show significant repigmentation after excimer laser treatment of chemical or mechanical leukoderma.

- i) **Ghazi et al.⁸ (2012)** treated a 50-year-old Indian man with Fitzpatrick skin type V at the University of Medicine and Dentistry, New Jersey, to evaluate the efficacy of the **308-nm excimer laser** for chemical leukoderma. Patient had macular depigmentation on the upper lip caused by hair dye containing p-phenylenediamine and hydrogen peroxide. He received 39 treatments, starting at 200 mJ/cm² and increasing to 1400 mJ/cm². Complete repigmentation was achieved without side effects, suggesting the excimer laser is effective and safe for chemical leukoderma.
- ii) **Jung et al.⁹ (2017)** conducted a study at St. Vincent's Hospital, Korea, to evaluate the 308-nm excimer laser for treating laser therapy-induced punctate leukoderma. The study focused on a 25-year-old man who developed depigmented macules on the neck after Q-switched Nd laser treatment. The excimer laser was applied twice weekly, starting at 175 mJ/cm² and incrementing by 25 mJ/cm². Complete repigmentation was achieved after 58 sessions over seven months, with no adverse effects. The study highlights the excimer laser as an effective modality for this condition.
- iii) **Weigelt et al.¹⁰ (2020)** at the University of Miami presented a case of thymol-induced chemical leukoderma in a 48-year-old Black woman. The patient developed depigmentation around all ten nail folds after using a thymol-containing product. She received 32 treatments with a 308-nm excimer laser, starting at 250 mJ/cm² and increasing to 1,190 mJ/cm². Partial repigmentation was achieved, particularly on the left hand. The study highlights the excimer laser as an effective treatment for chemical leukoderma.

d) **Alopecia Areata**

⁷ Brenninkmeijer EE, Spuls PI, Lindeboom R, van der Wal AC, et al. Excimer laser vs. clobetasol propionate 0.05% ointment in prurigo form of atopic dermatitis: a randomized controlled trial, a pilot. *Br J Dermatol* 2010;163:823–31.

⁸ Ghazi, S., Hexsel, C. L., Orengo, I., & Rendon, M. (2012). Treatment of Chemical Leukoderma Using a 308-nm Excimer Laser. *Dermatologic Surgery*, 38(2), 328–331. DOI: 10.1111/j.1524-4725.2011.02268.x

⁹ Jung, J. Y., Lee, W. J., & Kwon, I. H. (2017). Treatment of Laser Therapy-Induced Punctate Leukoderma Using a 308-nm Excimer Laser. *Lasers in Medical Science*, 32(5), 1171–1174. DOI: 10.1007/s10103-017-2247-5.

¹⁰ Weigelt, N., Goldstein, N. B., & Orlov, S. J. (2020). Thymol-Induced Chemical Leukoderma Treated with 308-nm Excimer Laser. *International Journal of Dermatology*, 59(8), 996–998. DOI: 10.1111/ijd.14873

- i) **Zakaria et al.¹¹ (2004)** conducted a prospective intraindividual study at Hôpital de l'Archet, France, to evaluate the efficacy of the **308-nm excimer laser** for alopecia areata (AA). Nine patients with different AA subtypes were treated twice weekly for up to 24 sessions. Results showed significant hair regrowth in patients with alopecia areata partialis (AAP), achieving 50-100% regrowth. The treatment was well-tolerated, with mild erythema as the only reported side effect.
 - ii) **Raulin et al.¹² (2005)** conducted a split-side study in Germany, involving six patients with localized alopecia areata (AA). Patients received twice-weekly 308-nm excimer laser treatments on one side of the scalp, while the other side served as a control. Results showed 85% regrowth in treated areas, compared to minimal improvement (5%) in untreated areas. The treatment was well-tolerated, with mild erythema as the only side effect. The study highlights the excimer laser's efficacy and safety for localized AA.
 - iii) **Al-Mutairi¹³ (2007)** conducted a prospective study at Farwaniya Hospital, Kuwait, to evaluate the 308-nm excimer laser for alopecia areata (AA). The study included 18 patients (4 children and 14 adults) with 42 recalcitrant patches, including one case of alopecia totalis. Lesions were treated twice weekly for 12 weeks, while untreated patches served as controls. Hair regrowth was observed in 41.5% of treated patches, with scalp lesions showing the highest response (76.5%). Side effects were minimal, indicating the laser's safety and efficacy for scalp AA.
- e) **Other Indications**
- i) **Beggs et al.¹⁴ (2015)** conducted extensive literature review by searching PubMed, MEDLINE, and ClinicalKey to find articles pertaining to the use of the **308-nm excimer laser** across various dermatological indications, including Psoriasis, Vitiligo, Atopic Dermatitis, Leukoderma, Alopecia Areata, Mycosis Fungoides, Cutaneous T-Cell Lymphoma, Lymphoproliferative Disorders, Granuloma Annulare, Langerhans Cell Histiocytosis, Lichen Planus, lichen planopilaris, and Localized Scleroderma. The review showed excimer laser's efficacy and safety across all these indications

Given that descriptor changes can be time-consuming and will leave many patients stranded without adequate care in the interim, we urge CMS to create a G-code to maintain patient access. It is worth noting that more than 30% of excimer laser usage for CMS patients is for non-psoriasis indications. A G-code will ensure continued access to this essential therapy for these patients.

Additionally, we emphasize that CMS decisions significantly influence commercial payers, where non-psoriasis indications represent a larger proportion of excimer laser usage, particularly among younger, non-Medicare patients.

¹¹ Zakaria, W., & Passeron, T. (2004). 308-nm Excimer Laser Therapy in Alopecia Areata. *Journal of the American Academy of Dermatology*, 51(5), 837–838. DOI: 10.1016/j.jaad.2004.07.029

¹² Raulin, C., Weiss, R. A., & Werner, S. (2005). Die Excimer-Laser-Therapie der Alopecia areata: Halbseitige Evaluation eines neuen Therapieverfahrens. *Journal der Deutschen Dermatologischen Gesellschaft*, 3(12), 910–915. DOI: 10.1111/j.1610-0387.2005.05665.x.

¹³ Al-Mutairi, N. (2007). 308-nm Excimer Laser for the Treatment of Alopecia Areata. *Dermatologic Surgery*, 33(12), 1483–1487. DOI: 10.1111/j.1524-4725.2007.33297.x.

¹⁴ Beggs S, Short J, Rengifo-Pardo M, Ehrlich A. Applications of the Excimer Laser: A Review. *Dermatol Surg*. 2015;41(11):1201-1211. doi:10.1097/DSS.0000000000000485

For example, United Healthcare's updated policy (effective 12/01/2024) is attached in Appendix C, highlighting the discontinuation of excimer laser coverage for vitiligo. This change is expected to impact thousands of vitiligo patients, **particularly patients of color**, who rely on excimer laser treatment for vitiligo management.

STRATA Skin Sciences reiterates its request for a meeting with CMS to discuss these issues and see if there is a path for at least partial correction before the rule is effective on January 1, 2025.

2) **Practice Expense**

The other critical issue was the response of CMS that it had not received adequate information on the costs of the laser and related supplies and maintenance. We are providing additional invoices and data related to these expenses that we believe will address the agency's concerns. STRATA was not consulted by AMA RUC on this data, so we have not yet had an opportunity to bring these issues directly to AMA RUC. STRATA also understands that CMS currently does not account for a 'subscription model' in calculating direct expenses for the fee schedule. Consequently, our comments and supporting (real-world) data are based on the 'direct sales' model which CMS uses.

Below, we have provided the data supporting the calculation of equipment cost formula, which accounts for years of useful life, utilization rate, purchase price, interest rate, maintenance, and minutes per year of use.

With STRATA having a direct line of sight into the actual use of most (over 75% of the approximately 1,200) excimer laser devices utilized by providers across the United States, STRATA's analysis relies on real-world data, which we can make available to CMS. As indicated in our previous communications, CMS has **overestimated** the utilization rate of excimer lasers at 50%, while real-world utilization is closer to 10%¹⁵. The actual utilization can be easily supported not only by STRATA's data (collected from the individual users) but most importantly from actual claims submitted by providers to CMS over the years. Furthermore, with a CPT descriptor change that restricts excimer laser use to psoriasis alone (which account for 70% of CMS excimer procedure use during 2022), the utilization rate is expected to decline further to approximately 7%. Again while we were not privy to the data upon which CMS relied, it is inconceivable that the utilization rate which CMS calculated accounted in any respect for the elimination of reimbursement for vitiligo and other inflammatory skin diseases.

Based on that **real world data** of device utilization, the direct Practice Expense (PE) cost, calculated using CMS's own equipment formula, is \$99.88, \$105.14 and \$120.91 for CPT code 96920, 96921 and 96922 respectively as shown below:

¹⁵ On average, dermatologists perform 344 excimer laser treatments per device annually, with each treatment requiring approximately 38–46 minutes of excimer laser use. This amounts to a total utilization of nearly 15,000 minutes per year, resulting in an effective utilization rate of 10%.

	CMS 2025 Proposed	Actual	Projected Updated CPT Code (Only Psoriasis)	Notes
Purchase Price	\$151,200			Source: CMS-1807-P_PUF_Equip.xlsx
Interest Rate	5.50%			Source: https://public-inspection.federalregister.gov/2024-14828.pdf
Maintenance Expense	0.05			
Usable Life (Years)	5			Source: CMS-1807-P_PUF_Equip.xlsx
Annual Equipment Cost	\$39,427			Formula = Purchase Price + (Purchase Price*Interest Rate)/ Usable Life + Purchase Price* Maintenance Expense
Minutes per year	150,000			Source: CMS-1807-P_PUF_Equip.xlsx
Utilization Rate	50%	10%	7%	Source: Proposed - CMS-1807-P_PUF_Equip.xlsx; Actual - Estimated based on STRATA Sales Data from 1,232 excimer lasers Between (2018-2023) performing 344 average treatment per year; Projected - Estimated based on % of Psoriasis in 2022 CMS excimer procedures
Effective Minutes per Year	75,000	15,000	10,500	Formula = Minutes Per Year * Utilization Rate
Per Minute Cost	\$0.59	\$2.63	\$3.75	Formula = Annual Equipment Cost/ Effective Minutes per Year
Minutes Excimer Use - 96920	38			Source: CMS-1807-P_PUF_Equip.xlsx
Minutes Excimer Use - 96921	40			
Minutes Excimer Use - 96922	46			
Direct PE 96920 ¹⁶	\$22.42	\$99.88	\$142.69	Formula = Per minutes Cost* Minutes Excimer Used
Direct PE 96921	\$23.60	\$105.14	\$150.20	
Direct PE 96922	\$27.14	\$120.91	\$172.73	

Additionally, CMS currently assumes a maintenance cost of \$7,560 (based on a 5% maintenance rate applied to a purchase price of \$151,200). However, excimer lasers are technical devices with substantially higher maintenance costs. The annual service cost for the excimer laser is \$30,000, as shown in the attached example invoices (Appendix D). Appendix D also contains a service invoice for \$44,000 for laser chamber replacement.

Moreover, CMS does not include the costs of consumable gas (code EQ154) and the optical delivery system (code EQ155) in the direct PE cost. These items were included in the calculation for CPT codes 96920-96922 until 2013. The current cost of a gas cylinder (EQ154) is \$6,300, excluding labor and shipping costs, and the optical delivery system (EQ155) is \$7,429. Example invoices are attached as Appendix E.

Lastly as emphasized in earlier communication to CMS, excimer laser is clinically and economically favorable treatment option for patients, providers and CMS for various indications (As shown in clinical Study attached in Appendix F). CMS's proposed and final 2025 rule threatens the access of this therapy for patients.

¹⁶ It is worth noting that under the subscription model, STRATA's usage agreement offers pricing of \$80, \$83, and \$100 for CPT codes 96920, 96921, and 96922, respectively. These usage agreement rates are lower than the correct direct PE cost as should be calculated using the equipment formula based on real-world data

STRATA respectfully makes the following requests to CMS:

1. Create a G-code for excimer laser treatment of inflammatory skin diseases.
2. Include real-world data on excimer laser utilization rates in the practice expense calculation.
3. Adjust the maintenance cost in the practice expense calculation to reflect the actual cost of maintaining excimer laser devices.
4. Reinstate the costs of consumable gas (code EQ154) and the optical delivery system (code EQ155) in the practice expense calculation.

In conclusion, we hope that CMS will find this additional information helpful and persuasive. We look forward to the opportunity to meet directly with CMS staff to review this information, along with other material previously submitted, at the agency's earliest convenience.

Thank you for your attention to these issues and the concerns of patients and physicians as expressed in the comments on the rulemaking. We look forward to meeting with you and members of your team.

Yours truly,

STRATA SKIN SCIENCES, INC.



Dr. Dolev Rafaeli
Chief Executive Officer