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September 4, 2024

Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS 1807-P  
P.O. Box 8016  
Baltimore, MD 21244-8016

RE: CY 2025 Physician Fee Schedule Proposed Rule [CMS-1807-P]

Dear Administrator Brooks-LaSure:

STRATA Skin Sciences (Horsham, PA) manufactures and distributes the XTRAC<sup>®</sup> 308 nanometer (nm) xenon chloride excimer laser used by dermatologists since 2003 to treat a variety of inflammatory skin diseases, including psoriasis, atopic dermatitis, vitiligo, and leukoderma, among others. This therapy is useful for many skin conditions and is a cost effective, patient preferred, intervention.

Currently more than 4,000 dermatologists in over 1,200 unique offices provide the excimer laser cost-effective therapy for their patients for a variety of inflammatory skin diseases.

XTRAC first obtained regulatory clearance by the US Food and Drug Administration in 2001 for the intended use of UVB phototherapy for psoriasis and vitiligo. In 2003 the indications for use were expanded by FDA to include atopic dermatitis and leukoderma.

We are including as part of these comments a Data Compendium (Appendix B) that provides background on the medical need for the laser; information on the FDA clearances; summaries of the many clinical trials that support the use of the excimer laser; and a list of some of the health plans that also cover the service, as does Medicare.

STRATA Skin Sciences and its predecessor PhotoMedex has manufactured the XTRAC since 2001 and is also the owner of the Pharos<sup>™</sup> (as of 2021) brands of excimer lasers. Currently, XTRAC and Pharos are the only FDA-cleared excimer laser devices available in the United States.

Physicians have used CPT codes 96920, 96921 and 96922 to bill for these laser services since January 1, 2003. These codes were first approved by the American Medical Association's CPT

Editorial Panel in 2002. The unfortunate decision by that same panel in 2023 (effective January 1, 2024) to limit the codes to just the indication for psoriasis has prevented physicians from using this technology to its full accepted range, as any skin condition other than psoriasis can only be billed using a miscellaneous code. This limitation prevents Medicare beneficiaries, among other patients, from obtaining this effective treatment that had previously been available for more than twenty years. The coding change now denies access to this care for individuals who had come to rely on it to manage their skin health and prevents anyone who newly develops any condition that is not psoriasis from receiving the benefit of this care. It should be noted that the limitation of the code use to psoriasis has directly effected patients with conditions and access limitations that are more relevant to patients of color (due to the effect these diseases have on quality of life) and accessibility (due to the potential limitations, side effects and the very high out-of-pocket cost of other treatment modalities).

STRATA sells the XTRAC excimer laser to private dermatology practices as well as hospital facilities . STRATA is the only supplier available for clinical training and technical support to those practices (the “direct sale” model). In addition to the all-out sale and support services, STRATA also places XTRAC excimer lasers at dermatologist offices at no upfront cost and charges a fee per use for the laser under a usage agreement (as defined by CMS – the “subscription model”). Of the approximately 1,200 excimer laser devices operating in the United States, about 900 are devices that are based on the subscription model – some 75%.

STRATA understands that currently CMS does not consider this “subscription model” in the calculation of direct expenses for the fee schedule. Therefore, our comments and the data provided to support them will reflect the “direct sales” model. However, if CMS would like more information on the “subscription model”, STRATA would be pleased to provide that additional data. However, as STRATA has a direct line of sight to the actual use of most of the excimer laser devices in the United States, Strata’s analysis is relying on that real-world data, which can be made available to CMS as well.

Although the RUC recent surveys report changes in MD time to perform the procedure, resulting in reduced RVU recommendations, it should be noted that the way the procedure is performed today is essentially unchanged from the earlier time study so reductions in MD time would not be expected, particularly in the amounts suggested both by RUC and CMS. We believe the MD survey should be redone, with a population that reflects **actual users** of the device.

In the discussion of the laser therapy in the 2025 proposed rule for Medicare’s physician fee schedule, CMS suggests that using its equipment cost per minute formula yields direct practice expense costs of \$21.22, \$22.40, and \$25.94 for CPT codes 96920, 96921 and 96922. STRATA will demonstrate that using those values would result in reimbursements so far below the actual costs of performing the services that most dermatology offices in the U.S. would not be able to

cover the cost of purchasing an excimer laser device. Under CMS's 2025 proposed rule assumptions, a dermatology office would need to perform at least 1,150 excimer laser procedures per year to breakeven on the purchase cost of an excimer laser. That volume of procedures is approximately 3.5 times higher than the actual current use. Based on use data from 1,232 unique excimer laser devices during the years 2018 – 2023, **typical** utilization is 344 treatments per excimer laser device per year<sup>1</sup>.

This data includes Medicare as well as other commercial payors procedures. Thirty to forty percent of this utilization is for non-psoriasis inflammatory skin disease conditions. The code changes mean that the typical practice will see excimer laser procedure use reduction of approximately one third of historic amounts.

Based on the actual utilization (344 average annual treatments per device), the average direct PE cost for one excimer treatment should be no less than \$90.45 to achieve breakeven on the cost of purchase of an excimer laser<sup>2</sup>. If only Psoriasis treatments are covered, that breakeven direct PE cost goes substantially higher to \$129.65 to \$151.79 per treatment.

The STRATA usage agreement pricing of \$80, \$83, and \$100 and average percentage use of 68%, 20%, and 12% for CPT codes 96920, 96921, and 96922 respectively leads to an average direct PE cost for excimer laser treatments to be \$83 under the usage agreement/ subscription model, which is lower than the required \$90.45 to achieve an economic breakeven under an excimer laser purchase model as proposed by the CMS (See assumptions and calculations in Appendix A)<sup>3</sup>.

It should be noted that when RUC reviewed the cost of the excimer laser, it made changes to the cost elements that are not reflective of the actual sales cost of the excimer laser, or its cost of maintenance<sup>4</sup>.

STRATA Skin Sciences does not believe that dermatologists will be able to maintain effective excimer laser usage for their patients under these circumstances. It is unfortunate that poor

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<sup>1</sup> See detail in table included in Appendix A.

<sup>2</sup> See assumptions and calculation in Appendix A below

<sup>3</sup> While STRATA's comments refer to the "direct sale" model that uses Medicare data, 75% of the market devices and over 90% of the providers using the excimer laser operate under the STRATA Usage Agreement.

<sup>4</sup> Excimer laser (code EQ161) cost was reduced from \$160,000 in 2018 to \$155,580 in the suggested 2025 rule. That is neither reflective of the actual STRATA sales price (that has gone up) or the other elements (service, inflation, training etc.) that have gone up over the years. CMS used to refer to actual cost elements (e.g. the cost of consumable gas, code EQ154, and the optical delivery system, EQ155 – both items that are replaced multiple times annually and did not update these respective costs. In 2024, the cost of a gas cylinder is \$6000 (not including labor and delivery) vs. \$1,500 in 2013 and zero in the suggested rule. STRATA has attached an example for such an invoice as Appendix C

coding and disagreement over relative values between CMS and the AMA RUC may lead to denying this medically helpful treatment to US patients. Due to historical misalignment between the actual cost of the excimer laser for a dermatology provider and the actual practice expense RVUs reimbursed amount, between the years 2019 (161,552 treatments reimbursed by CMS) and 2022 (111,296 treatments reimbursed by CMS), over 33% of the CMS excimer procedures have already migrated to potentially **more expensive** treatment modalities (as shown by increased biologics use for Psoriasis patients).

The excimer laser is the most cost-effective treatment option for CMS and other payers as compared to other available treatment modalities for psoriasis. According to a recently published peer reviewed study<sup>5</sup> the migration of patients from the excimer laser treatment to an alternative modality will greatly increase the cost. The study summarizes and concludes that “... *excimer laser ... translates into substantial clinical and economic benefits for patients with plaque psoriasis – excellent safety, rapid response, high likelihood of PASI%75 reductions, potential for clearance (PASI%92), relatively few care days, and a cost that is lower than biologics, NB-UVB, ... and possibly even some generic topicals ... Collectively, these benefits translate into improved cost efficiency.*”

To address these concerns, STRATA makes the following recommendations to CMS:

1. Request that the AMA CPT Editorial Panel develop a new code for excimer laser treatment of inflammatory skin diseases. It should be broad enough to cover the current list of inflammatory skin conditions that respond to excimer laser treatment (Psoriasis, Vitiligo, Atopic dermatitis, Leukoderma, Alopecia areata, Chronic recalcitrant dermatitis, Lichen planus, Cutaneous T-cell Lymphoma (e.g. Mycosis fungoides/ Sezary Syndrome), Parapsoriasis, Pityriasis lichenoides chronica, Pruritus, Urticaria pigmentosa, Superficial mycoses (e.g., dermatophytosis [ringworm])<sup>6</sup>) and flexible enough to include new conditions where the excimer laser may be proven to be effective. In the interim, we ask that CMS create a G code that is based on the 2022 CPT codes for the excimer laser to substitute for the 2024 revisions, so that at least Medicare beneficiaries will be able to easily access this important therapy. Adding these disease states is supported by the fact that private payors currently and historically have recognized these codes for the treatment of other inflammatory disease states in addition to psoriasis. See Appendix D for examples of several policies of private insurers which support that position.
2. Request that when AMA RUC values the revised codes that it include in its analysis the actual use data by the providers in addition to the actual cost of the device if purchased and the minimum number of procedures required to achieve a clinic economic viability if ownership is chosen. We believe that incorporating this data will help set more accurate practice expense RVUs than is now the case.

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<sup>5</sup> Marchetti A, Bhutani T, Lockshin B, Siegel DM, Behringer F. Therapies for Psoriasis: Clinical and Economic Comparisons. *J Drugs Dermatol.* 2020;19(11):1101-1108. doi:10.36849/JDD.2020.5510 the **Marchetti Study**

<sup>6</sup> Based on existing commercial payor coverage policies.

3. CMS and RUC should resolve their differences over the calculation of physician work, using new survey data from panels that include dermatologists familiar with excimer laser treatments that would fall under the revised codes. STRATA points out that there has been no device or procedure use technological change that warrants such a dramatic change in treatment time.
4. Recognizing that all these actions can take time, we request that CMS make no changes to coding, billing, or payment for the laser treatment under consideration and revert to the 2023 codes and RVU calculations. Such an interim step will avoid disruption of patient care not only for Medicare beneficiaries but also for other patients covered by commercial health plans, Medicaid, Tricare, and any other health plans that use the Medicare calculations as the basis for their reimbursement.

STRATA appreciates the opportunity to submit these comments. We also request the opportunity to have an in-person meeting with appropriate CMS staff to discuss our concerns and recommendations.

STRATA SKIN SCIENCES, INC.

A handwritten signature in black ink, appearing to read 'Dolev Rafaeli', written in a cursive style.

Dr. Dolev Rafaeli  
Chief Executive Officer

## Appendix A

### Comparison of CMS suggested practice expense RVUs, actual cost as demonstrated with real world data and STRATA's usage agreement costs

#### 1. CMS 2025 Proposed Rule:

- a. Excimer laser purchase price: \$155,580 with a 5-year **usable life**<sup>7</sup>
- b. Proposed direct PE costs for excimer laser: \$21.22, \$22.40, and \$25.94 for CPT codes 96920, 96921, and 96922 respectively

*Under CMS's proposed 2025 rule, a dermatology office needs at least 1,150 procedures per year to breakeven on the purchase cost.*

#### Calculation:

- a. **Annual** Cost of Excimer Laser:  $\$155,580 / 5 = \$31,116$  (not including maintenance and interest)<sup>8</sup>
- b. Breakeven number of required excimer treatments:  $\$31,116 / (\$21.22 \text{ to } \$25.94) = 1,200 \text{ to } 1,466$  treatments per year

*To reach breakeven on the purchase price, a provider would need to use device more than 1,200 to 1,466 times a year.*

*Not reaching breakeven for practitioners with excimer lasers will drive dermatology providers to either increase use of excimer devices or switch treatments to alternative more expensive modalities for their patients.*

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<sup>7</sup> Per CMS assumption the purchase cost of excimer laser does not include maintenance, training of staff, interest, etc. As noted above, this cost does not reflect the actual Strata sales price, which is higher. Nor does it include actual cost of maintenance.

<sup>8</sup> The cost of ownership (\$155,580) was surveyed in 2012. While STRATA is usually not selling devices, and most of the devices used in the market are based on the Usage Agreement, the current cost of ownership of an XTRAC Momentum 308 nm excimer laser is \$189,500 including the cost of acquisition and 5 years of service. That cost does not include additional maintenance requirements that are beyond the standard service contract (e.g. consumables, gas cylinder replenishment – which vary by practice use).

2. **Actual Excimer Laser Utilization Data<sup>9</sup> (actual use data for 1,232 unique excimer laser devices during the years 2018-2023 under STRATA Usage Agreement):**

Under STRATA’s usage agreement, dermatology practices purchase a specific number of treatments from STRATA. This purchase allows them to unlock a specific number of treatments that an excimer laser can perform. Once dermatology offices use these treatments, they need to purchase more treatments to continue the excimer laser use. Hence, STRATA has visibility to the utilization of all the excimer lasers that are under STRATA’s usage agreement

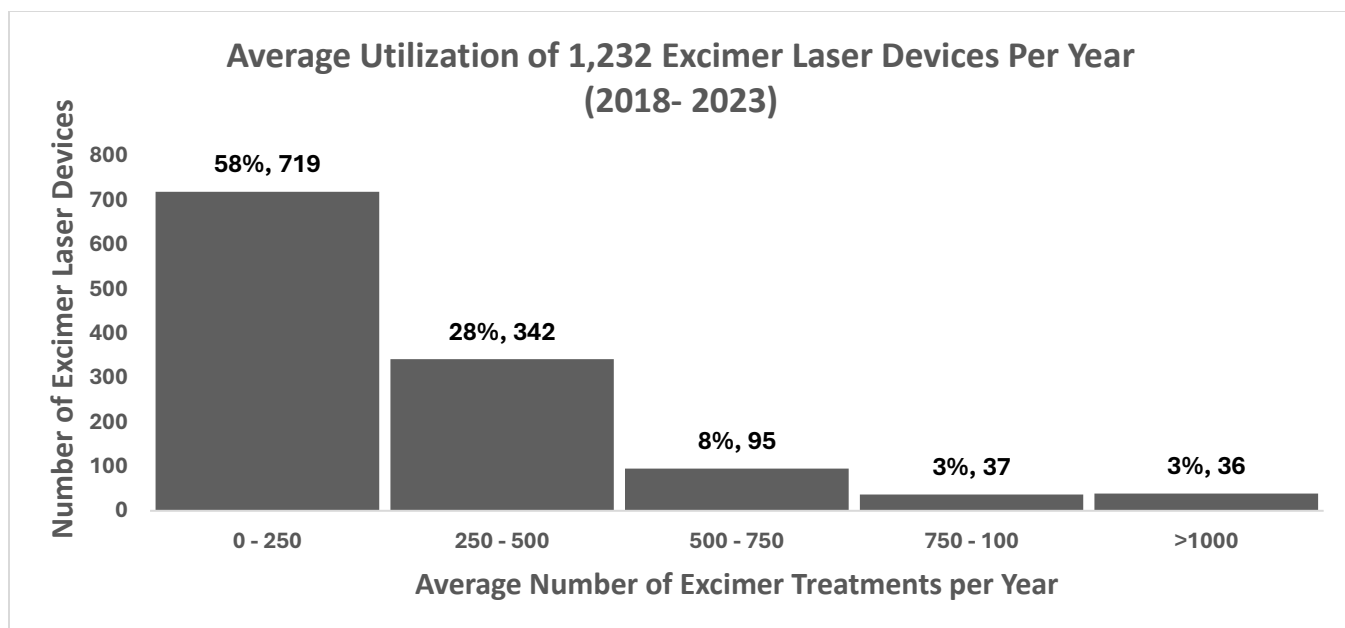
- a. Average Utilization: 344 treatments per excimer laser device per year
- b. High Utilization (>1000 treatments/year): Only 36 unique excimer laser devices per year

<b>Year</b>	<b>2018</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>	<b>Average</b>
<i><b>N = Number of unique Excimer Lasers under Strata Usage Agreement (Basis for Data Below)</b></i>	697	753	733	822	853	807	<b>778</b>
<b>Average number of Excimer Treatments per Device</b>	<b>403</b>	<b>421</b>	<b>276</b>	<b>343</b>	<b>328</b>	<b>291</b>	<b>344</b>
<b>Standard Deviation</b>	369	369	283	322	328	307	<b>330</b>
<b>Number of excimer laser devices with more than 1000 Treatments</b>	47	54	16	36	34	26	<b>36</b>
<b>Number of excimer laser devices with more than 500 Treatments</b>	190	220	89	166	151	118	<b>156</b>

The table above shows the excimer laser utilization data for 1,232 unique lasers between 2018 – 2023.

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<sup>9</sup> STRATA Data on File.



1. Between 2018 – 2023, the majority (58%) of the excimer laser devices performed less than 250 excimer treatments per year
2. Only 3% of the excimer laser devices performed more than 1,000 treatments per year

Hence, given the current utilization rates, **as supported by the actual data**, and the proposed direct PE costs of \$21.22, \$22.40, and \$25.94 for CPT codes 96920, 96921, and 96922 respectively, **most dermatology offices in the US cannot cover the cost of purchase of an excimer laser device.**

It should be noted that approximately 30-40% of treatments are currently performed for non-psoriasis indications. With the CPT code descriptor change implemented in early 2024, excimer laser utilization is expected to decrease further to (205 - 240 treatments), making it even more challenging for dermatology offices to justify the cost of purchasing an excimer laser device under a capital purchase model.

### ***3. Appropriate Direct PE Cost for excimer laser treatments under purchase model***

***Based on actual utilization data (344 average annual treatments), the average direct PE cost per excimer treatment should be at least \$90.45 to breakeven on the cost of purchase of an excimer laser (not including maintenance and interest). If only Psoriasis treatments are covered, that breakeven direct PE cost goes substantially higher to \$129.65 to \$151.79 per treatment, as shown by the calculation below.***

Calculation



- a. Cost of Excimer Laser per year (without maintenance and interest): \$155,580/ 5 years = \$31,116 per year
- b. Direct PE cost per treatment: \$31,116 / 344 average treatments per year = \$90.45
- c. Direct PE cost per treatment (for only Psoriasis Indication): \$31,116/ 205 - 240 average treatments per year = \$129.65 to \$151.79 per treatment

#### **4. Direct PE Cost for excimer laser treatments under STRATA Usage Agreement Model**

The STRATA usage agreement pricing of \$80, \$83, and \$100 and average percentage usage of 68%, 20%, and 12%<sup>10</sup> for CPT codes 96920, 96921, and 96922 respectively leads to an average direct PE cost for excimer laser treatments to be \$83 under the usage agreement model, which is much lower than \$87.91 under an excimer laser purchase model as proposed by CMS.

##### Calculation

- a. Average direct PE cost for excimer laser =  $\$80 \times 68\% + \$83 \times 20\% + \$100 \times 12\% = \$83$

	<b>96920</b>	<b>96921</b>	<b>96922</b>
<b><i>Per treatment cost under STRATA usage agreement</i></b>	\$80	\$83	\$100
<b>% use of excimer treatments under each code</b>	<b>68%</b>	<b>20%</b>	<b>12%</b>

Hence, by offering a usage agreement model STRATA **enables** 4,000+ dermatology providers in over 1,200 unique dermatology offices to offer the safe and effective excimer treatment modality to thousands of their patients.

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<sup>10</sup> Based on 2022 CMS Data for excimer laser codes. In 2022 68% (75,369), 20% (22,206) and 12% (13,721) of total 111,296 excimer laser treatments were performed under 96920, 96921 and 96922 CPT code respectively.

Appendix B  
Data Compendium

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Appendix C  
Example of an invoice for replacement of gas, windows

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## Appendix D

Examples of Private Payor Coverage for Inflammatory Diseases states in addition to psoriasis