

NS 100

NeuroSolutions 100

(PNS/PENS)

**In Office Trigemino-cervical (TCN),
Vagal Nerve (VN) and Cranial
Nerve Stimulator (CNS) for Painful
Diabetic Neuropathy**

FDA cleared Class II Medical Device

Offering relief for chronic pain
associated with diabetic neuropathy

Covered by most insurance carriers

Temporary device worn for up to 20
days with results lasting up to 6
months



KATHRINE DALLIS MATANGOS

ORIGINAL RESEARCH article

Front. Neurosci., 25 August 2025

Sec. Autonomic Neuroscience

Volume 19 - 2025 |

<https://doi.org/10.3389/fnins.2025.1644961>

This article is part of the Research Topic
Expanding Therapeutic Horizons with Non-Invasive Vagus Nerve Stimulation

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Combined minimally invasive vagal cranial nerve and trigeminocervical complex peripheral nerve stimulation produces prolonged improvement of severe painful peripheral neuropathy and hyperglycemia in type 2 diabetes



Peter S. Staats^{1,2*}



Alyssa Staats^{1,3}



Brittany Mikhael^{1,4}



Jason Chen^{1,5}



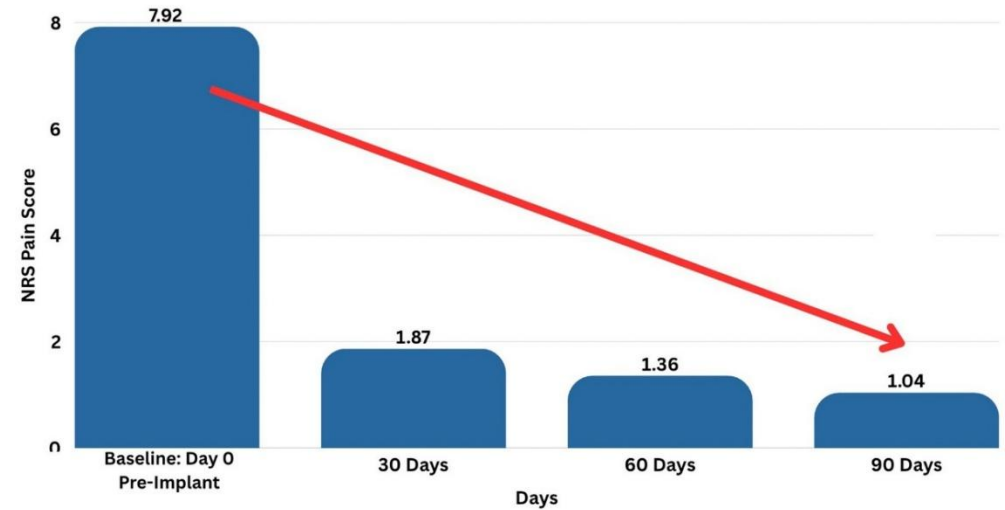
Eric Azabou^{1,6,7}



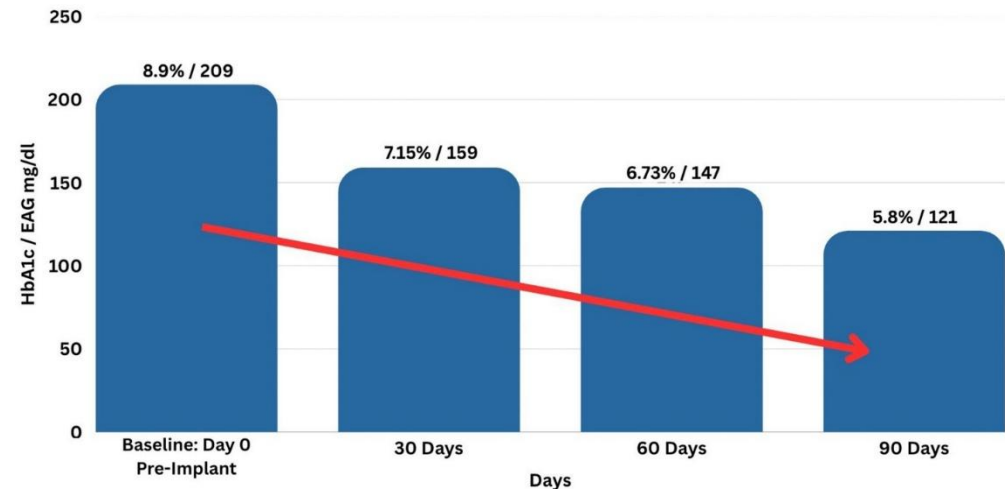
Claire-Marie Rangon^{1,6,7}

<https://doi.org/10.3389/fnins.2025.1644961>

NRS Pain Score Values - 87% Reduction in 90 Days

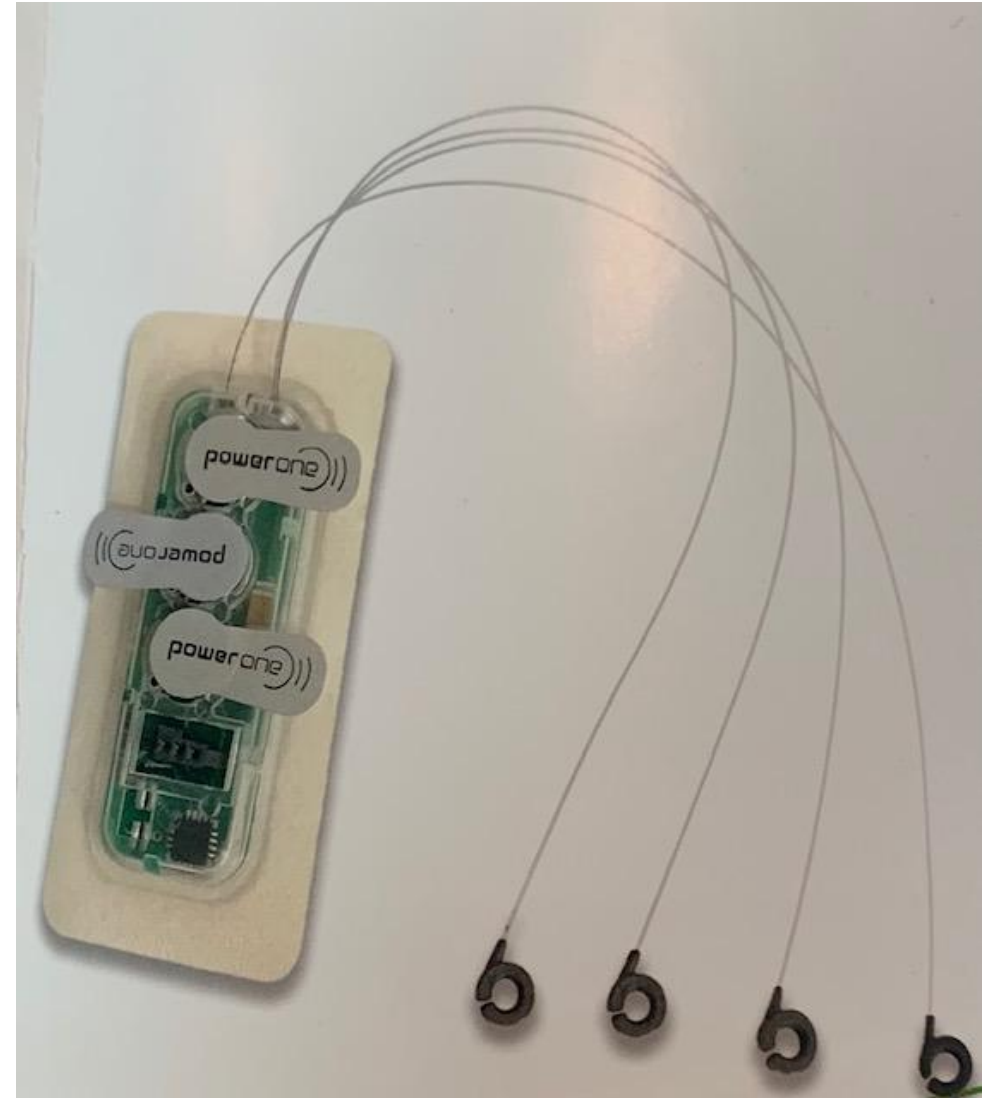


Blood Glucose Level - 37% Reduction in 90 Days



Overview of the Solution

- **Neuromodulation Division of the FDA** has cleared NeuroSolutions 100 as a Class II Medical Device - **trial Peripheral Electrical NeuroStimulator (PENS/PNS/CNS)** for use as a **non pharmacologic aid to reduce the symptoms of chronic pain associated with diabetic neuropathy.**
- 4 independent, programmable, titanium electrode arrays precisely implanted activating:
 - **TrigeminoCervical Nucleus**
 - C1-2-3 Cervical Spinal Roots (LON,GAN)
 - Trigeminal Nerve (ATN)
 - **Vagus Nerve (ABVN)**
 - Opioid, Nicotinic, Cannabinoid Receptors
 - PANS > SANS
 - Cholinergic Anti-inflammatory Pathway
 - Vagal Control of the Metabolic State
 - Neuroendocrine
 - Immune Response
- Can increase quality of life and functionality by minimizing medication side effects (e.g. opioids, NSAIDS, tricyclics, anti-epileptics, etc.), improving diagnostic accuracy (e.g. narcotic hyperalgesia) and potentially modifying end-organ disease state. (Level 1 RCT)



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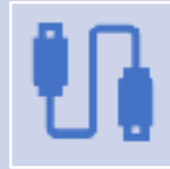
Trigemino-cervical and Vagal Nerve Stimulation for Painful Diabetic Neuropathy (PDN)

- Successful clinically in mitigating pain for up to 6 months**
- Can decrease need for prescription pain medication and aid in opioid withdrawal treatment
- Potentially diagnose and Remove Narcotic Hyperalgesia from PDN pain presentation
- Potentially improve patients' function, insomnia, depression, anxiety and quality of life
- Potential Central Antidromic Inhibition of WDN of Dorsal Horn

****Potential Vagal Control of Metabolic State - Improvement in Inflammatory bidirectional reflexes and Glucose to maintain Pain control**



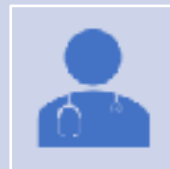
Device Treatment Process



Prior to implant the device is programmed as:
Fixed Vs. Sweep Receptor Specific Activation
through a **Programmable Technical Unit (PTU)**
based on **patient specific dx e.g. Diabetic Neuropathy**



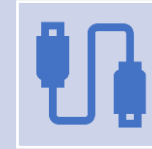
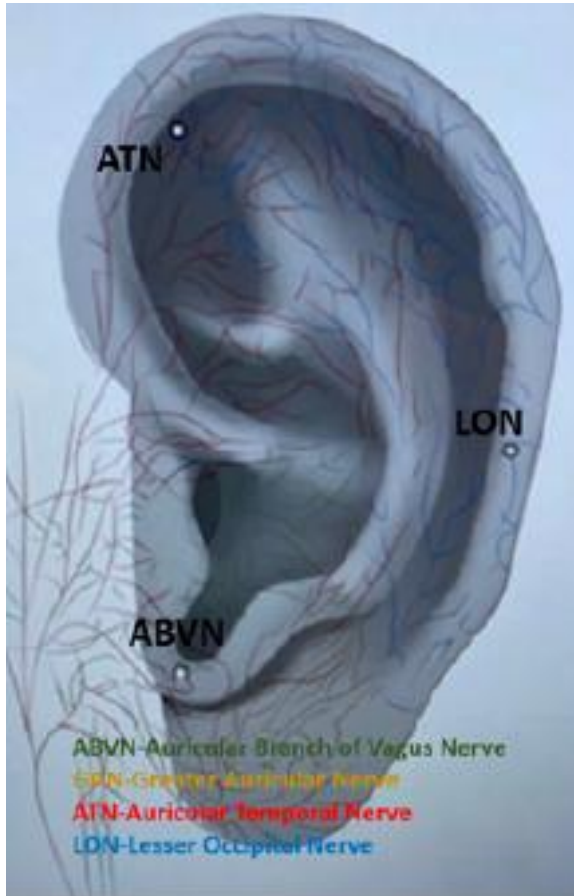
An anatomic ear illustration is generated by the PTU with
real-time closed loop impedance drop feedback to
precisely locate the diagnosis specific nerves (e.g.
ATN, ABVN, LON, GAN, etc.).



Provider **precisely implants and programs the 4 independent titanium electrode arrays on the diagnosis specific nerves**, wearing device up to 20 days.
(Continuum of Care - Pain, Blood Sugar, Function, ...)

70%+ of patients mitigate pain up to 6 months

Device Treatment Process (continued)



Patient cannot get the device wet or tamper with the device.



Patient returns to the facility to have the device removed by medical professional.

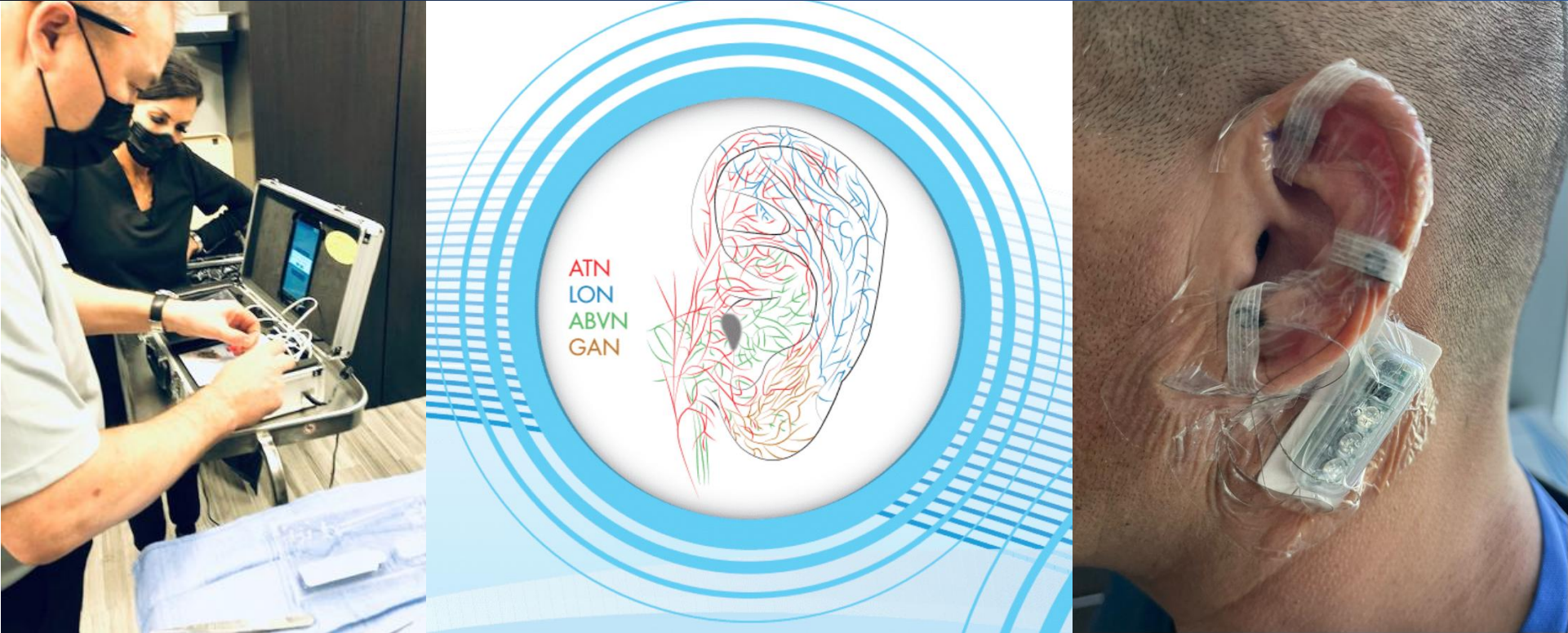


Contraindications:

Hemophilia, pregnancy, cognitive impairment, implantable cardiac devices*, indwelling/implantable stimulator devices**

*i.e.; pacemaker ** i.e.; deep brain stimulator, spinal cord stimulator).

NS100 Office/Outpatient Implant



Real-time closed loop impedance drop locates the TCN (ATN, LON, GAN) and Vagus (ABVN) for precise titanium electrode array implantation.

20-minute procedure worn for 20 days (MD/DO and NP-PA in certain states)

Receptor Specific Programming Activation
(Fixed vs. Sweep)



Medical Necessity / Prior Authorization Requirements

Provider notes include:

- Patient demographics
- Insurance information
- Patient face sheet
- Minimum of 3 months of chronic pain associated with diabetic neuropathy and corresponding diabetic neuropathy diagnosis codes
- Failed modalities
- Patient history of pain management
- Pain scale 5 or greater
- Device recommendation from provider
- Letter of Medical Necessity (LOMN)

Provider Profiles

- Neurology
- Pain Management
- Primary Care
- Endocrinology
- Internal Medicine
- General Practitioners
- Rheumatology





Advantages of the Program

- Allows providers to confirm that patients' pain is responsive to NS100 and follow the provider's treatment plan
- Helps providers reduce the number of patients receiving pain management treatment using opioids while reducing pain
- Predetermination/prior authorization process is managed by NeuroSolutions 100 to mitigate denials
- Significant revenue stream to facility



Program Summary

- PNS/PENS is a Programmable Class II Medical Device
- FDA cleared in 2021 for the treatment of chronic pain associated with individuals suffering from diabetic neuropathy
- Four strategically placed titanium electrode arrays implanted directly into the nerve endings, preprogrammed by the Programming Technical Unit based on the patient's diagnosis
- Temporary device worn for 20 days with possible results lasting up to 6 months
- Predetermination/billing process is managed by NeuroSolutions 100 to mitigate denials
- One-on-one training provided by NeuroSolutions 100 team
- Device is covered by most Commercial Carriers and Medicare

ROI | 10 Devices | Texas Facility

NAME	DOS	REMIT DATE	PRIMARY INSURANCE	TOTAL PRIMARY PAID	SECONDARY INSURANCE	TOTAL SECONDARY PAID 20%	TOTAL PAID (Primary + Secondary)	TOTAL ROI (Total paid - device cost)
Patient 1	1/22/2025	3/18/2025	UHC	\$8,106.74	N/A	\$0.00	\$8,106.74	\$4,956.74
Patient 2	1/31/2025	3/10/2025	UHC	\$8,106.74	N/A	\$0.00	\$8,106.74	\$4,956.74
Patient 3	1/29/2025	3/10/2025	UHC	\$8,116.54	N/A	\$0.00	\$8,116.54	\$4,966.54
Patient 4	2/12/2025	3/4/2025	MEDICARE TX	\$9,443.44	Mutual of Omaha	\$2,360.86	\$11,804.30	\$8,654.30
Patient 5	2/26/2025	3/14/2025	MEDICARE TX	\$9,443.44	AARP	\$2,360.86	\$11,804.30	\$8,654.30
Patient 6	2/28/2025	4/7/2025	MEDICARE TX	\$9,443.44	BCBS	\$2,360.86	\$11,804.30	\$8,654.30
Patient 7	12/13/2024	4/1/2025	AETNA	\$6,788.10	N/A	\$0.00	\$6,788.10	\$3,638.10
Patient 8	3/5/2025	4/11/2025	MEDICARE TX	\$9,443.44	Mutual of Omaha	\$2,360.86	\$11,804.30	\$8,654.30
Patient 9	3/5/2025	4/11/2025	MEDICARE TX	\$9,443.44	Aetna	\$2,360.86	\$11,804.30	\$8,654.30
Patient 10	3/7/2025	4/11/2025	MEDICARE TX	\$9,443.44	AARP	\$2,360.86	\$11,804.30	\$8,654.30
TOTAL				\$87,778.76		\$14,165.16	\$101,943.92	\$70,443.92

ROI | 10 Devices | North Carolina Facility

NAME	DOS	REMIT DATE	PRIMARY INSURANCE	TOTAL PRIMARY PAID	TOTAL MEDICARE SECONDARY PAID 20%	TOTAL PAID (Primary + Secondary)	TOTAL ROI (Total paid - device cost)
Patient 1	2/28/2025	3/1/2025	AETNA	\$11,339.55	\$0.00	\$11,339.55	\$8,189.55
Patient 2	5/5/2025	6/18/2025	UHC	\$7,041.91	\$0.00	\$7,041.91	\$3,891.91
Patient 3	1/27/2025	3/5/2025	UHC	\$11,663.03	\$0.00	\$11,663.03	\$8,513.03
Patient 4	7/31/2025	10/8/2025	BCBS NC	\$10,151.42	\$0.00	\$10,151.42	\$7,001.42
Patient 5	7/31/2025	10/8/2025	BCBS NC	\$11,645.90	\$0.00	\$11,645.90	\$8,495.90
Patient 6	2/27/2025	4/1/2025	MEDICARE NC	\$9,389.22	\$2,347.30	\$11,736.52	\$8,586.52
Patient 7	2/27/2025	4/1/2025	MEDICARE NC	\$9,389.22	\$2,347.30	\$11,736.52	\$8,586.52
Patient 8	5/7/2025	6/10/2025	MEDICARE NC	\$9,389.22	\$2,347.30	\$11,736.52	\$8,586.52
Patient 9	5/7/2025	6/10/2025	MEDICARE NC	\$9,389.22	\$2,347.30	\$11,736.52	\$8,586.52
Patient 10	5/13/2025	6/13/2025	MEDICARE NC	\$9,389.22	\$2,347.30	\$11,736.52	\$8,586.52
TOTAL				\$98,787.91	\$11,736.50	\$110,524.41	\$79,024.41

ROI | 10 Devices | South Carolina Facility

NAME	DOS	REMIT DATE	PRIMARY INSURANCE	TOTAL PRIMARY PAID	TOTAL MEDICARE SECONDARY PAID 20%	TOTAL PAID (Primary + Secondary)	TOTAL ROI (Total paid - device cost)
Patient 1	10/7/2025	11/2/2025	UHC	\$9,378.51	\$0.00	\$9,378.51	\$6,228.51
Patient 2	3/14/2025	4/14/2025	UHC	\$11,667.87	\$0.00	\$11,667.87	\$8,517.87
Patient 3	3/14/2025	5/9/2025	UHC	\$11,667.87	\$0.00	\$11,667.87	\$8,517.87
Patient 4	7/17/2025	8/20/2025	MEDICARE SC	\$9,316.12	\$2,329.03	\$11,645.15	\$8,495.15
Patient 5	7/25/2025	8/27/2025	MEDICARE SC	\$9,316.12	\$2,329.03	\$11,645.15	\$8,495.15
Patient 6	10/3/2025	11/26/2025	MEDICARE SC	\$9,319.44	\$2,329.86	\$11,649.30	\$8,499.30
Patient 7	10/3/2025	11/26/2025	MEDICARE SC	\$9,319.44	\$2,329.86	\$11,649.30	\$8,499.30
Patient 8	10/20/2025	12/2/2025	MEDICARE SC	\$9,323.20	\$2,330.80	\$11,654.00	\$8,504.00
Patient 9	10/17/2025	12/2/2025	MEDICARE SC	\$9,323.20	\$2,330.80	\$11,654.00	\$8,504.00
Patient 10	7/14/2025	8/28/2025	MEDICARE SC	\$9,316.12	\$2,329.03	\$11,645.15	\$8,495.15
TOTAL				\$97,947.89	\$16,308.41	\$114,256.30	\$82,756.30