

Interventional depression care - extended beyond the clinic



Proliv®Rx - First and only FDA approved, physician directed, home-based brain stimulation therapy for patients who haven't adequately responded to antidepressants

Next-generation brain stimulation for major depressive disorder

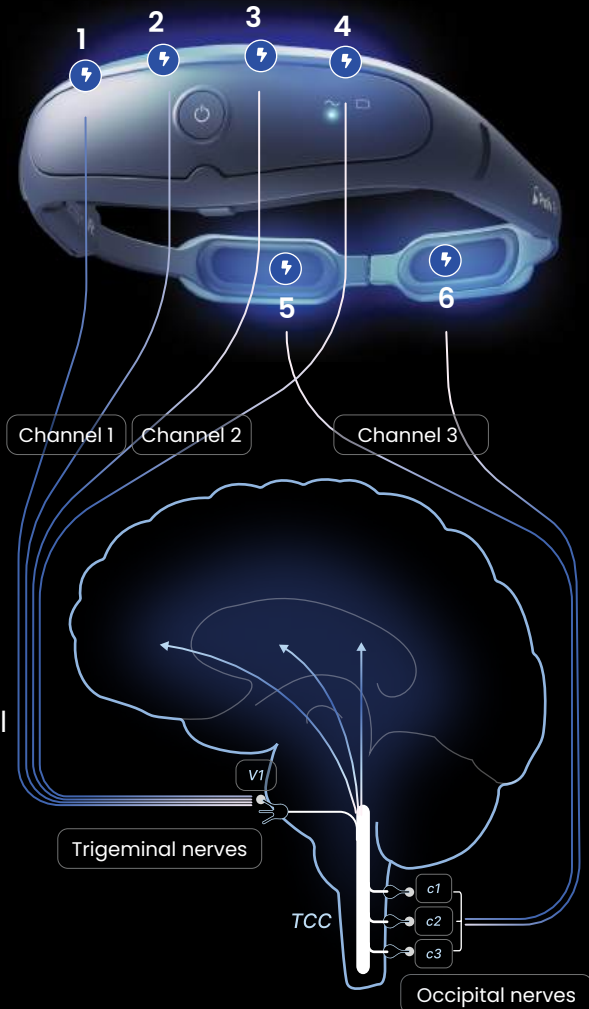
- ✓ Physician-directed, at-home therapy
- ✓ Built for patients with inadequate response to antidepressants
- ✓ Multi-channel brain stimulation

Differentiation snapshot

| Therapy | Setting | Scalability | Access Barriers |
|-----------------------------|-------------|-------------|-----------------|
| Proliv[®]Rx | At-home | ✓ High | ✓ Low |
| TMS | In-clinic | ✗ Limited | ✗ High |
| ECT | In-hospital | ✗ Limited | ✗ High |
| Spravato | In-clinic | ✗ Limited | ✗ High |

How it works

- Multi-channel brain stimulation.
- Concurrent activation of the trigeminal and occipital nerve pathways.
- Afferent inputs converge at the brainstem.
- Modulation of brainstem nuclei and associated neurotransmitters release.
- Further projections to subcortical and cortical regions linked to depression.



Suitable patients

- ✓ Adults (22+) with a confirmed diagnosis of unipolar MDD.
- ✓ Inadequate response to ≥ 1 antidepressant trial.
- ✓ Moderate-to-severe depressive symptoms (e.g., HDRS17 ≥ 16).
- ✓ No psychotic or bipolar features.
- ✓ Owns or has access to a smartphone for twice daily at-home treatment.
- ✓ Can adhere to a structured, app-guided protocol.
- ✓ Without contraindications to the treatment.

Patient journey snapshot



Therapy consult



Training remote or in-clinic



Complete guided sessions



Review progress and next steps

Dedicated support for you and your patients

We have a dedicated team ready to support you and your patients on their journey with Proliv®Rx.

- Onboarding training for clinicians and patients.
- Ongoing patient check-ins for regimen support.

Phone: (844) 277-6548

Email: support@prolivrx.com

Text: (754) 812-1935

Fax: (954) 775-0151

Clinical efficacy

Proliv®Rx is the first and only at-home brain stimulation therapy proven effective in a prospective, randomized controlled study in patients with difficult to treat depression who previously failed antidepressant medication.

Key outcomes

87%

Improved by one or more depression severity levels

After 8 weeks of therapy.
Depression severity levels: very severe, severe, moderate, mild, no depression.

70.7%

Achieved clinically substantial improvement

After 16 weeks of therapy.
Reduction of ≥ 7 points in HDRS-17

31.7%

Reached full remission

After 16 weeks of therapy

56%

Reached mild or no depression

After 16 weeks of therapy

96%

Fully adhered to the treatment protocol

During 16 weeks of therapy

Scan to read the full study publication



Safety Overview

Proliv®Rx was well tolerated in clinical studies, with no device-related unanticipated serious adverse events reported. Observed adverse events were generally mild to moderate in severity and transient in nature. The most commonly reported adverse events included scalp numbness, localized skin reactions at the electrode sites, and headache.

Indication for use

The Proliv®Rx System provides focal external Combined Occipital and Trigeminal Afferent Stimulation (eCOT-AS) treatment. It is intended as an adjunctive treatment for Major Depressive Disorder (MDD) in adults who failed to achieve satisfactory improvement from at least one previous antidepressant medication, for patients' use at home or in clinic. It is a prescription only device.

Contraindications

The Proliv®Rx System is contraindicated for use in patients with:

- A history of intracranial surgery.
- Recent traumatic brain injury (TBI) (less than three months).
- A metal implant or shrapnel in their head, except of dental implants
- An implanted neurostimulator or electronic device in your head such as a cochlear implant or brain pacemaker.
- A cardiac pacemaker or an implanted or wearable defibrillator.
- Skin lesions, scars, or inflammation at the region of the stimulating electrodes.



Proliv®Rx offers an accessible and effective solution for patients whose depression is unresponsive to medications, many of whom have endured years of persistent symptoms. This therapy has the potential to become an essential tool in the mental health treatment landscape.



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