AURIMOD

Intramurale Erstattung einer innovativen Methode in der Schmerztherapie - Erfahrungen am Beispiel der aurikulären Vagus Nerv Stimulation

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Experts in auricular Vagus Nerve Stimulation

VISION & MISSION

We enable people to live an autonomous and healthy life

by

delivering effective personalized, minimal-invasive, and non-pharmacological therapies to restore health of patients by using cutting-edge biomedical technology.

We focus on the sustainable health and quality of life of patients.

VIVO

Auricular Vagus Nerve Stimulation

Minimal-invasive

Personalized

Clinically proven

Safe

CE 0483

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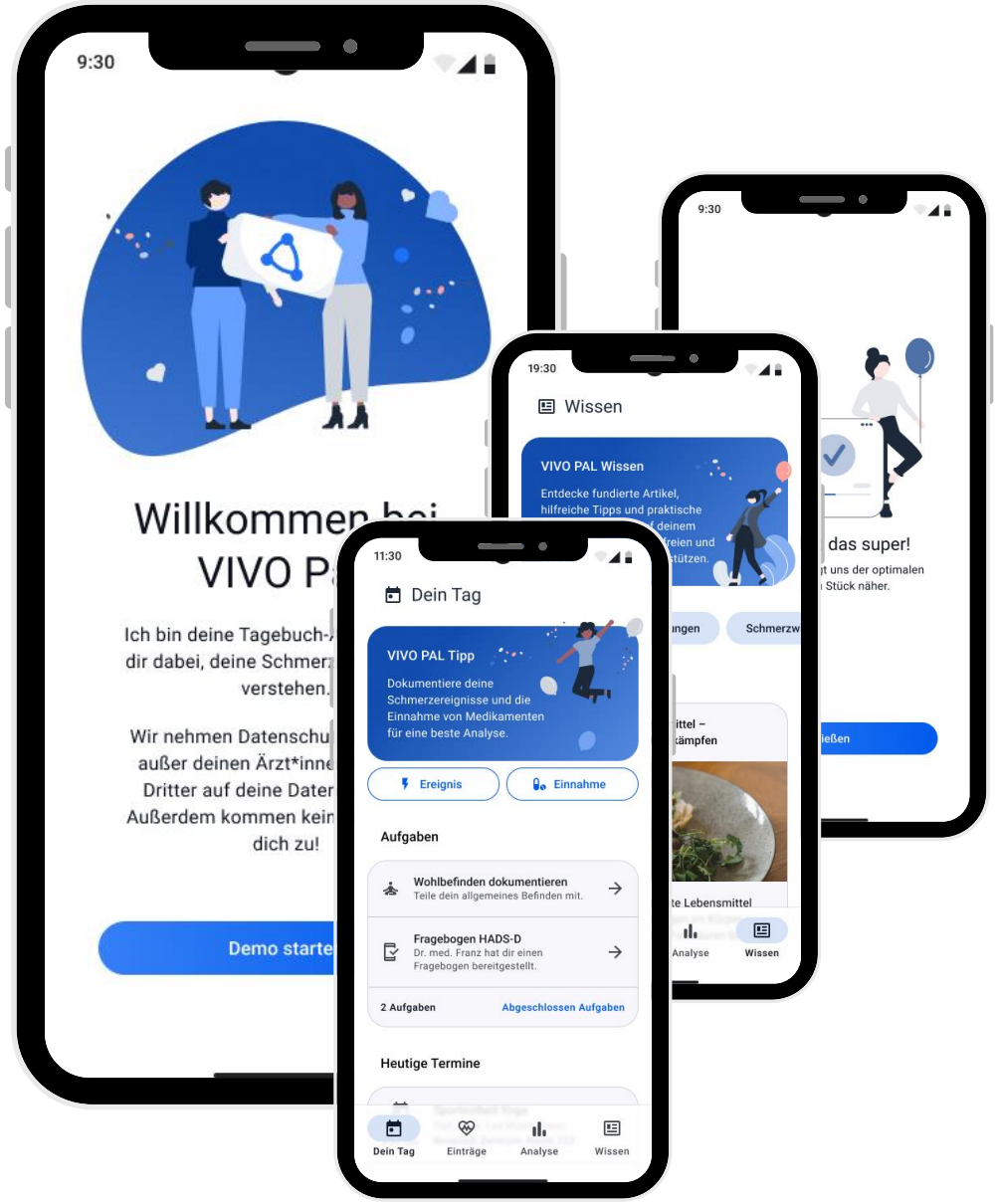
VIVO® Pal App

The next generation of therapy management support

Support doctors & patients through an amazing day to day journey and find out what drives & motivates your patients



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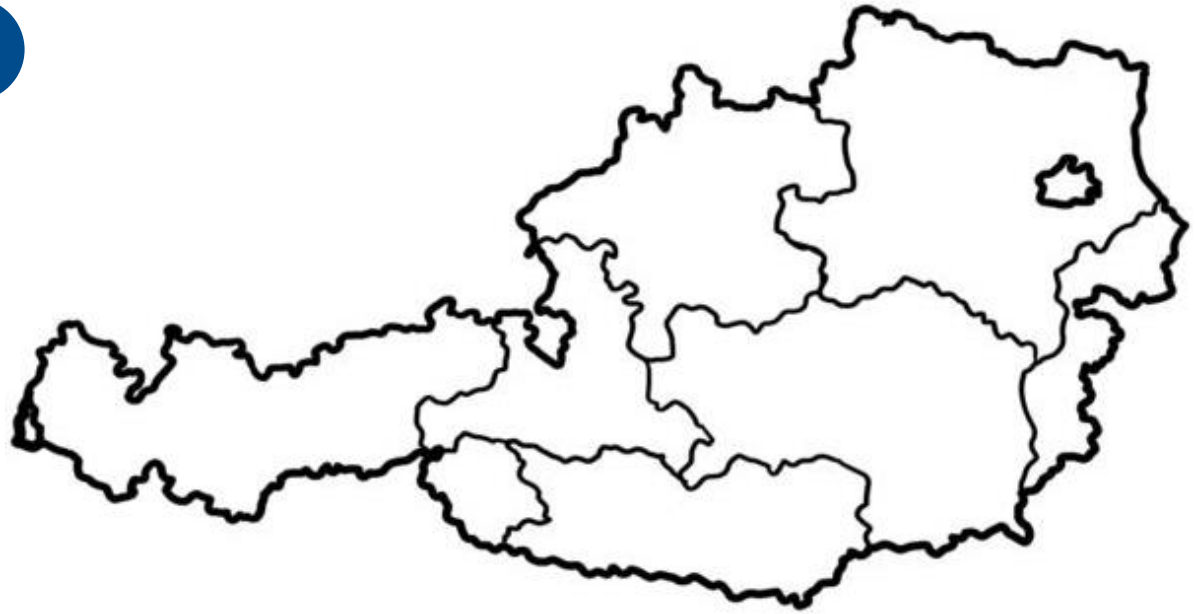

Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz

Dachverband der Sozialversicherungsträger

Österreichische Gesundheitskasse ÖGK

Versicherungsanstalt öffentlich Bediensteter, Eisenbahn und Bergbau BVAEB

Sozialversicherung der Selbständigen SVS

Pensionsversicherungsanstalt PVA

Allgemeine Unfallversicherungsanstalt AUVA

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Erstattungssektoren

Ambulanter Sektor – extramural

- Niedergelassener Bereich
- Verhandlung nötig
  - Leistungserbringer (Ärztekammer)
  - Sozialversicherung bzw. Krankenversi-cherungsträger

Stationärer Sektor – intramural

- Spitalsfinanzierung
  - Landesgesundheitsfond
    - Erhobene Steuern durch Bund, Länder & Gemeinden
    - Sozialversicherung
  - Privatkrankenanstalten-Finanzierungsfonds

→ Fallpauschalensystem (LKF)

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LKF - Leistungsorientierte Krankenanstaltenfinanzierung

- verbindliche Grundlage für die einheitliche Leistungsdokumentation
  - Basierend auf medizinischen Leistungen in codierter Form:

AP560	Anlage eines Systems zur aurikulären Vagusnervstimulation (LE=je Sitzung) Anlage der Elektroden in vagal innervierten Bereichen der Ohrmuschel (Fossa Triangularis, Cymba Conchae, Cavum Conchae), Verbindung mit dem Stimulator und Befestigung des Stimlators (hinter dem Ohr am Hals). Schmerztherapie bei ausgewählten Indikationen:

- 889 stationäre Leistungen
- 912 Leistungen, die sowohl ambulant als auch stationär zu erfassen sind
- 325 Leistungen, nur ambulant mit 2025 Fokus digital Healthcare & bessere Erstattungsmöglichkeiten ambulant

In jeder Fachabteilung soll ein ständig der Abteilung zugehöriger Facharzt für die Verschlüsselung der medizinischen Leistungsdaten verantwortlich und für alle im Zusammenhang mit der Leistungsdokumentation auftretenden Fragen zuständig sein.

Vgl. Leistungskatalog BMSGPK 2025

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Vorschläge für neue Leistungen

Krankenanstalten

↓

Trägergesellschaft

↓

BMSGPK

- *Vorschläge sind bis 31. Oktober des laufenden Kalenderjahres zu übermitteln, um für das übernächste Modelljahr berücksichtigt zu werden. (Hint: Krankenhäuser können frühere Fristen haben)*
- *Dem Vorschlag sind auch jeweils eine Musterkalkulation (Leistungsbezogen Device + Personal) und die wesentlichen veröffentlichten Publikationen anzuschließen.*

Vgl. Leistungskatalog BMSGPK 2025

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Vorschläge für neue Leistungen

Aufnahme neuer und die Differenzierung bestehender Leistungen

Zusammenlegung von Leistungen

Neuaufnahme einer abrechnungsrelevanten Leistung

- Leistung ist neu bzw. zur Abbildung des medizinischen Fortschritts erforderlich
- Die Leistung ist fachlich etabliert
- Adäquate wissenschaftliche Evidenzen liegen vor
- Die Leistung ist von ökonomischer Relevanz (Kosten, Frequenz)

Vgl. Leistungskatalog BMSGPK 2025

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Health Technology Assessment (HTA)

systematischer, evidenzbasierter Prozess… zum Vergleich zu anderen (neuen oder bestehenden) Gesundheitstechnologien

Klinische Dimensionen

- Feststellung eines gesundheitlichen Problems und Ermittlung bestehender Gesundheitstechnologien
- Prüfung der technischen Eigenschaften der zu bewertenden Gesundheitstechnologie
- Relative Sicherheit
- Relative Wirksamkeit

Nichtklinische Dimensionen

- Kostenabschätzung und wirtschaftliche Bewertungen
- Ethische Aspekte
- Organisatorische Aspekte
- Soziale Aspekte
- Rechtliche Aspekte

Vgl. https://www.sozialministerium.at/Themen/Gesundheit/Gesundheitssystem/Health-Technology-Assessment-(HTA).html

Health Technology Assessment (HTA) - Beispiel

HTA Austria
Austrian Institute for Health Technology Assessment GmbH

Electrical auricular vagus nerve stimulation for pain

Systematic Review

AIHTA Decision Support Document: 138 | ISSN-online: 1998-0469

1 Background

1.1 Overview of the disease, health condition and target population

Schmerz = Hauptgrund für Inanspruchnahme von medizinischer Hilfe

Pain is an unpleasant sensory and emotional experience that is associated with actual or potential tissue damage. It is the main reason people seek medical care [1]. There are three main types of physical pain [2-5].

nozizeptiver Schmerz: Schädigung von nicht-Nervengewebe, verschwindet (normalerweise) nach Heilung wieder

- *Nociceptive:* This is the most common type of pain. It results from damage to non-neural tissue and tends to go away once the affected body part heals. Nociceptive pain is further categorised as either somatic (originating in peripheral tissues such as skin, muscle and bone) or visceral (occurring in organs of the abdomen and chest). This type of pain is associated with trauma, such as fractures, burns, muscle tears and sprains; muscle spasms; degenerative changes resulting from normal wear and tear, such as primary osteoarthritis; and visceral pathologies such as ulcers, renal stones and pancreatitis.

neuropathischer Schmerz: Krankheiten oder Verletzungen, die das somatosensorische Nervensystem (NS) betreffen

- *Neuropathic:* This type of pain arises from diseases or injuries affecting the somatosensory nervous system. Conditions associated with neuropathic pain include nerve or nerve root compression (e.g., radiculopathy, carpal tunnel syndrome and trigeminal neuralgia); exposure to toxins (e.g., chemotherapy); metabolic diseases such as diabetes; ischaemia (e.g., peripheral vascular disease and diabetic neuropathy); trauma (e.g., postsurgical pain); infections (e.g., shingles and human immunodeficiency viruses); and inflammation (e.g., inflammatory demyelinating polyradiculoneuropathy).

noziplastischer Schmerz: unabhängig von Gewebs- oder Nervenschäden

- *Nociplastic:* This pain is caused by the activation of peripheral pain-related sensory pathways in the absence of actual tissue or nerve damage. Nociplastic pain can occur in isolation or in combination with nociceptive or neuropathic pain. It is often associated with bladder pain syndrome, fibromyalgia, chronic pelvic pain, irritable bowel syndrome, temporomandibular disorder, some types of tension-type headaches and non-specific back pain.

akuter Schmerz: plötzliches Auftreten, kurze Dauer und eine offensichtliche Ursache

chronischer Schmerz: langanhaltend, über die erwartete Heilungszeit hinaus

Pain can be further categorised as acute or chronic.[1], Acute pain is a psycho-physiological response to tissue trauma and re-lated inflammatory processes and has a valuable survival function. It has a sudden onset, short duration and an obvious cause [3]. In con-trast, chronic pain is a maladaptive pain that persists beyond the ex-pected healing time of injured tissues (three months according to In-ternational Classification of Diseases [6]) [2]. Chronic secondary pain is usually a symptom of another condition, whereas chronic primary pain is a disease unto itself. Examples of chronic primary pain conditions include fibromyalgia and complex regional pain syndromes, irri-table bowel syndrome and nonspecific low back pain [3]. The relevant International Classification of Diseases (ICD)-11 codes for the various acute and chronic pain conditions are listed in Table 1 1.

[1] **A0002** What is the disease or health condition in the scope of this assessment?

1.3 Features of the intervention

Vagusnerv (VN) = längster Hirnnerv

VN reguliert eine Vielzahl von Funktionen im Körper (z.B. Verdauung, Herzfrequenz und Blutdruck)

The cranial nerves are a set of twelve paired nerves that have motor and/or sensory functions and connect the brain with the head, neck and torso. The longest of these is the vagus nerve (cranial nerve X), which extends from the thoracic and visceral abdominal organs up to the higher cerebral centres of the locus ceruleus, dorsal motor nucleus of the vagus, medulla, amygdala, hypothalamus, parabrachial nucleus and thalamus [32-34]. The afferent fibres, which comprise 80% of the nerve, carry sensory information from the head, neck, thorax and abdomen to the brain, while the efferent fibres (constituting 20% of the nerve) carry motor information to the pharynx, larynx, trachea, heart, aorta, lungs and gastrointestinal tract (oesophagus, stomach, liver, pancreas and spleen). Consequently, the vagus nerve regulates a variety of functions within the autonomic, cardiovascular, respiratory, gastrointestinal, immune and endocrine systems, including digestion, heart rate, blood pressure, vascular resistance, airway diameter, respiration and reflex actions such as coughing, sneezing, swallowing and vomiting. The vagus nerve also appears to have a role in regulating the neuro-endocrine-immune axis, mood, pain and memory [33-35].

VN beeinflusst Schmerz durch Hemmung und Aktivierung von Mechanismen die, die Schmerzwahrnehmung beeinflussen

The vagus nerve is thought to modulate pain through its ability to inhibit inflammation, oxidative stress and sympathetic activity and to activate brain regions that influence pain perception, such as the thalamus, hypothalamus, left prefrontal cortex and the periaqueductal gray [32, 36].[10] Consequently, the vagus nerve has become an attractive target for addressing various diseases and pain-related conditions through neuromodulation, which is the manipulation of nervous system activity using either electrical or pharmaceutical agents to achieve a therapeutic benefit, such as pain relief [37, 38].

elektrische Vagusnervstimulation (VNS) seit 1994 in Europa bei Epilepsie zugelassen

Invasive VNS hat mehrere Nachteile im Zusammenhang mit der Drahtimplantation/-explantation und der Stimulation

Electrical vagus nerve stimulation (VNS) was approved in Europe as an adjunctive treatment for epilepsy in 1994 and for refractory depression in 2001. VNS has also been trialled as a potential treatment for other diseases, such as rheumatoid arthritis and heart failure [39, 40]. Invasive VNS involves wrapping a wire around the left vagus nerve in the neck and connecting it to an electrical nerve stimulator (or pulse generator) that is implanted under the skin on the left side of the chest. The device emits low-level pulses of electrical current that are transmitted via the wire along the vagus nerve to the brain. Despite its effectiveness, the mechanism of action of VNS is still not completely understood. The side effects related to wire implantation (infection and vocal cord paresis) and stimulation (hoarseness, voice changes and cough) have limited the intervention's application to patients who are resistant to conventional therapeutic strategies [41, 42]. An additional problem with invasive VNS is that the electrode wires are hard to remove without damaging the vagus nerve [43].

Alternative zur invasiven VNS = aurikuläre VNS (aVNS)

VN wird über Nervenbahnen in Ohrmuschel stimuliert

To avoid these difficulties, several devices have been designed to electrically stimulate branches of the vagus nerve located in the ear (auricular branch) or neck (cervical branch) either percutaneously (using a needle electrode) or transcutaneously (using a non-invasive surface electrode attached to the skin) [37-39, 44, 45].[11] Anatomical studies of the ear suggest that afferent vagus nerve distributions are located at the inner side of the tragus, the concha and

[10] **A0009** What aspects of the consequences/burden of disease are targeted by the technology?

[11] **B0002** What is the claimed benefit of the technology in relation to the comparators?

Vgl. https://eprints.aihta.at/1457/

Health Technology Assessment (HTA) - Beispiel

7 Recommendation

In Table 7-1 the scheme for recommendations is displayed and the according choice is highlighted.

Table 7-1: Evidence based recommendations for acute postoperative and chronic pain

	The inclusion in the catalogue of benefits is **recommended**.
X	The inclusion in the catalogue of benefits is **recommended with restrictions**.
	The inclusion in the catalogue of benefits is **currently not recommended**.
	The inclusion in the catalogue of benefits is **not recommended**.

Reasoning:

Population One: Acute postoperative pain

aVNS: sichere und wirksame Zusatztherapie bei Rebound-Schmerzen nach ACL-Rekonstruktion, jedoch nicht auf andere postoperative Schmerzen übertragbar

Reducing postoperative pain is important, not only for patient comfort and expediting recovery, but also for avoiding the development of CPSP. High certainty evidence from one RCT indicated that transcutaneous aVNS was superior to sham (both in addition to standard care) in reducing rebound pain after femoral nerve block, analgesia consumption, rescue medication usage and sleep disturbance during the first twelve hours after knee reconstruction surgery. Limited low certainty evidence does not support the use of aVNS for other type of acute postoperative pain. One large ongoing trial assessing aVNS versus sham treatment for the relief of pain in 600 patients undergoing arthroplasty in China is due for completion in July 2024, but the results from this may not be generalisable to other operative procedures. Based on this, a re-evaluation is recommended not before 2025.

1 laufendes RCT

Population Two: Chronic pain

aVNS: sichere und wirksame Zusatztherapie bei gastrointestinalen Erkrankungen bei 11 – 18-jährigen &

High certainty evidence from one RCT indicates that adjunctive percutaneous aVNS is more effective and as safe as adjunctive sham treatment in youth aged 11 to 18 years with pain-related gastrointestinal disorders, particularly irritable bowel syndrome. Lower certainty evidence from one RCT indicated that this may also be true for adults (18 to 75 years of age). There are currently no ongoing RCTs of aVNS for gastrointestinal disorders.

mögliche positive Effekte bei Migräne und myofaszialem Schmerzsyndrom

Adjunctive transcutaneous aVNS may also reduce pain in patients with episodic migraine without aura or myofascial pain syndrome, but the results should be interpreted with caution owing to the lower certainty of evidence for these indications.

11 laufende RCTs

Of the 11 ongoing RCTs identified, six are evaluating the use of aVNS in various chronic musculoskeletal conditions. There are currently no ongoing RCTs of aVNS for chronic migraine or other headaches. Based on this, the re-evaluation is recommended not before 2024.

Empfehlung: Aufnahme nur für ausgewählte Patient*innen

Based on the available evidence the inclusion of aVNS in the hospital benefit catalogue should be limited to selected patients.

Vgl. https://eprints.aihta.at/1457/

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Take Aways

- Kommunikation
- Einplanung einer Erstattungsstrategie
- Problemerkenntnis auf EU Ebene für digitale Produkte– EDiHTA
- Transparenz – Lobbyregister
- Interessenvertretungen
- Nachhaltige Etablierung (wenn ein Coding etabliert ist, muss es auch genutzt werden)

AURIMOD

Help us to bring our solution to those affected by chronic back pain.

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