



Germany opens the DiPA reimbursement pathway to support the adoption of digital health applications, underpinning the value of the #1 target market for Brain+’ first commercial dementia product, CST

- A significant event for Brain+ as DiPA can provide reimbursement coverage for the first Cognitive Stimulation Therapy (CST) product, expected to be launched in Germany in 2023
- The CST product fits well with the requirements of the DiPA reimbursement pathway. The goal of the DIPA is to reimburse products that stabilize patients' health with special training programs or facilitates communication with family members and nursing care professionals, and this is the same purpose as the product.
- The DIPA pathway can thus enable access to the Brain+ CST products for the 1 million Germans living with mild-to-moderate dementia, which is the target segment for the CST products.

As an essential part of Germany’s far-reaching digital healthcare act from 2021, a new reimbursement pathway has now been opened for digital care applications. The pathway is abbreviated DiPA in German from *Digitale Pflegeanwendungen* (*digital care applications*). The German Federal Institute for Drugs and Medical Devices (*BfArM*) is setting up the new procedure for verifying the reimbursability of digital care applications through this pathway.

Kim Baden-Kristensen, CEO of Brain+, commented on the news:

“Germany is a key market and is leading the charge in Europe for the adoption of digital health solutions. This is an important milestone for Brain+, as a centralized reimbursement channel, like the DIPA, will provide easier access for the 1 million Germans living with mild-to-moderate dementia to our CST product, which we plan to launch in 2023”

“We see the German initiative as only the beginning of a Europe-wide swing towards regulatory and reimbursement support for digital health solutions. Belgium has already followed, and France is next to copy the German models - and our digital products seem to fit well to the requirements of these new reimbursement channels.”

Watch Brain+ CEO & CCO discuss the DIPA in a short video here:

<https://vimeo.com/723479194/a8925c713a>

Launching Brain+ CST dementia products to the German market in 2023

The first dementia product of Brain+, Cognitive Stimulation Therapy (CST) – Therapist Companion, is developed to help dementia caregivers easily deliver CST to people with dementia in the clinic. It will be followed by a second product version, CST – Home Extension, which allows a person with dementia to receive CST in the comfort of their own home with the help of a caregiver.

Brain+ is progressing as planned with CST – Therapist Companion and expects to have the first product version ready before the end of 2022 and to launch in Denmark and Germany in 2023. The new German reimbursement options are key for commercial uptake, as they will allow people with dementia to get health insurance coverage for digital applications.

Brain+' Cognitive Stimulation Therapy Product has a good fit with the DiPA requirements

A DiPA is a digital care application that is designed to help patients cope better with everyday care. DiPAs can be used by care recipients to stabilize or improve their state of health through exercises (e.g., personalized memory games for people with dementia). They can also improve communication with family members and care professionals. DiPAs can be used either as an app on mobile devices (e.g. smartphones, tablets) or as a browser-based web application on a computer or laptop. (Source digital.iges.com).

Cognitive Stimulation Therapy is a psychosocial talk therapy, which facilitates meaningful conversations and improves communication between the person with dementia and their caregivers, and therefore has a good fit with these DiPA requirements.

Reimbursement & pricing levels in Germany of up to €600/year

The care insurance fund will pay up to 50 euros per month for a digital 'nursing' application. 1.5 million people are living with dementia. Of these, around 1 million have mild to moderate dementia, which is the target for the Cognitive Stimulation Therapy dementia product. Given actual reimbursement levels, the present addressable market for this segment in Germany alone is around €400 million. Brain+ believes it has a favorable leading position since no other vendors are known to be as far along as Brain+.

Other EU countries are following Germany

Many European countries have begun plans to implement similar approval and reimbursement processes. Belgium has launched a process called mHealthBELGIUM and in October of 2021 French President, Emmanuel Macron, announced France will launch a DiGA-like expedited reimbursement process in 2022.

Next for DiPA

In mid-November 2020, the German Federal Ministry of Health (BMG) published a draft law on the digital modernization of care and nursing (DVPMG). The draft law is expected to come into force soon, which essentially means that the process is officially available, and the first applicants will be able to apply

More on DiPA

Here's the link to the DiPA requirements:

<https://lnkd.in/ek3idq75>

A summary article on DiPA:

<https://digital.iges.com/diga/dipa - digital application in nursing care/#>

About BRAIN+ [BRAINP]

Brain+ is a pioneer of Digital Therapeutics for dementia and Alzheimer's disease, including disease stages of prodromal/mild cognitive impairment, and pre-clinical/subjective cognitive impairments.

PROBLEM:

Dementia is a terrible condition, crippling a person's independence and putting a heavy burden also on the family. This puts an enormous emotional burden on the patients and their loved ones. As cognitive abilities deteriorate, behaviors change, and independence is lost. The complexity of the underlying pathology of dementia has so far made it hard for traditional pharmaceutical companies to deliver effective treatments, and there is an increasing focus on new non-drug therapies that can pave the way to help relieve the heavy burden of dementia – for people living with the disease, their relatives and healthcare systems. With an aging population, dementia – and in particular Alzheimer's dementia – is a growing problem, threatening to overwhelm the health care systems of the world.

PURPOSE:

Making effective dementia treatment and prevention available to everyone in need, as digital therapeutics (also called 'Software-as-medicine').

CLINICAL TARGETS:

To slow cognitive decline, maintain functional abilities, preserve independence, and add more healthy years for people living with dementia; additionally, to prevent progression into dementia for people at risk of dementia.

SOLUTION:

Together with world-leading experts and institutions, we are digitizing the best-in-class, non-drug dementia therapies, making them available on regular digital devices – both in people's homes and at the clinics. A therapy here, simply means a person having to actively do something, interacting with a software program or another person, which is stimulating to the brain, or which results in changes in behavior that brings measurable health benefits. Our digital therapeutic solutions also benefit the caregivers in their work and can help ease the pressure on the health care systems.

DIGITAL & DRUGS:

Software-as-medical treatments can be used on their own or be combined with traditional drug treatments. We believe the future will combine the best of both the digital and the pharmacological world for mutually enhancing benefits, including synergies in compliance, patient engagement, and mechanisms of action for better health outcomes.

PERSONALIZED, DATA-DRIVEN MEDICINE:

We believe a key benefit of digital medicine is also to proactively collect and use data to create tailored and more effective personalized therapy experiences, and to help improve clinical and scientific practice, while always adhering to strict ethical standards of personal data protection.

OUR DNA:

We are a digital biotech company. Our technologies and products are being built on a deep understanding of the challenges and needs associated with dementia, rigorously tested, scientifically and clinically validated, and regulated as software-as-medical-devices (software-as-treatments). These treatments will be prescribed by health care professionals and paid for by health insurance or state health care.

PRODUCTS & TECH:

The company has developed three core technologies, which are undergoing clinical validation and further iterative development.

- **Cognitive Stimulation Therapy** is a dementia therapy that treats the main symptoms of dementia. This technology is the basis of the first dementia treatment product, 'Cognitive Stimulation Therapy – Therapist Companion', which will be launched in Denmark and Germany in 2023. A second product, called 'Cognitive Stimulation Therapy – Home Extension', is planned next.
- **Computerized Cognitive Training** is essentially like fitness exercises for the brain. The 2nd generation of this technology is currently being developed for use in the pre-stages of dementia, like mild cognitive impairment, or in people who are in high-risk groups for developing dementia.
- **Starry Night Test** is a special memory test, which was originally developed by Professor Masud Husain at Oxford University, and then further co-developed, gamified, and made scalable with Brain+, with the aim of doing early detection of Alzheimer's disease and monitoring of disease progression.

CLINICAL PIPELINE:

Brain+ is expecting results from 5 Pilot and Proof of Concept (PoC) studies in H2 2022 on the 3 core technologies, and 1 additional study in 2023. 4 trials (1 Pilot, 3 PoC) have been successfully concluded as of February 2022, with positive results for all three technologies.

POTENTIAL:

Currently, 50 million people are diagnosed with dementia globally, and this number is expected to triple to more than 150 million people by 2050. In the US, 1 in 3 seniors die with or of dementia.

In 2030, the global costs of dementia are expected to be \$2 trillion (or equal to 2/3rds of the entire health care budget of the USA), prospectively 1 in 3 people will die from dementia and the estimated market potential for digital dementia treatments approximately \$2-5 billion. Tapping into this market with effective digital solutions has the potential to generate revenue of hundreds of millions \$. Brain+ aims to commercialize its products based on licensing deals with strategic commercial partners for faster market penetration and global scaling.

TEAM:

We have built our knowledge base, know-how, and network of global expert collaborators over 10 years, and our technology portfolio is the results of R&D investments of over €10 million, which puts us in a unique position to become a global market leader in digital therapeutic solutions for dementia and Alzheimer's. We have a senior management team with a combined 100 years of track record, with backgrounds from companies such as Coloplast, Lundbeck, Novartis, and GN Hearing. This provides us the solid backbone needed, to change the way we treat and deal with dementia on a global scale.

PARTNERS & COLLABORATORS:

We believe collaborations give the best outcomes, and so we partner with the best minds and hearts in our eco-system; pharmaceutical leaders in Alzheimer's, such as Biogen and RoX Health, a subsidiary of Roche Germany; academic & clinical partners, such as Universities of Oxford, Nottingham, Aarhus, Gothenburg; patient organizations and NGOs, such as Alzheimer Europe, Alzheimer's disease international, and the European Brain Council.