Payment and Access for Early-Stage Alzheimer's Treatments

Public Webinar

Duke-Margolis Center for Health Policy

February 13, 2020

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Welcome and overview

- Project background
- Ongoing efforts
  - Overview of upcoming issue brief
- Proposed next steps
- Reaction comments
- Audience Q&A
- Closing remarks

Project background

Since 2017, Duke-Margolis has collaborated with The Global CEO Initiative for Alzheimer's Disease (CEOi) to:

- Facilitate input from a diverse group of stakeholders, including pharma, physicians, payers, government, and academics
- Convene expert workshops and conduct stakeholder interviews
- Address key challenges and propose practical policy strategies
- Previous work focused on:
  - Identifying treatment issues in current clinical practice
  - Exploring strategies to improve the diagnosis and screening of AD
  - Discussing how to leverage data and evidence to assess the value of AD therapies

Why focus on new payment methods?

- New, potentially disease-modifying drugs could bring significant changes to how AD is treated
- Yet, drugs that target early-stage AD raise concerns about high upfront and chronic treatment costs that may not translate to real-world benefits
- Given the long time horizon of AD progression, and variability of progression among patients, value may not be apparent until years after initial drug use

In 2019, Duke-Margolis held a closed expert workshop to discuss how payment reform could enhance access and understanding of new drugs, as well as areas where improved tracking and outcomes could lead to better coverage decisions

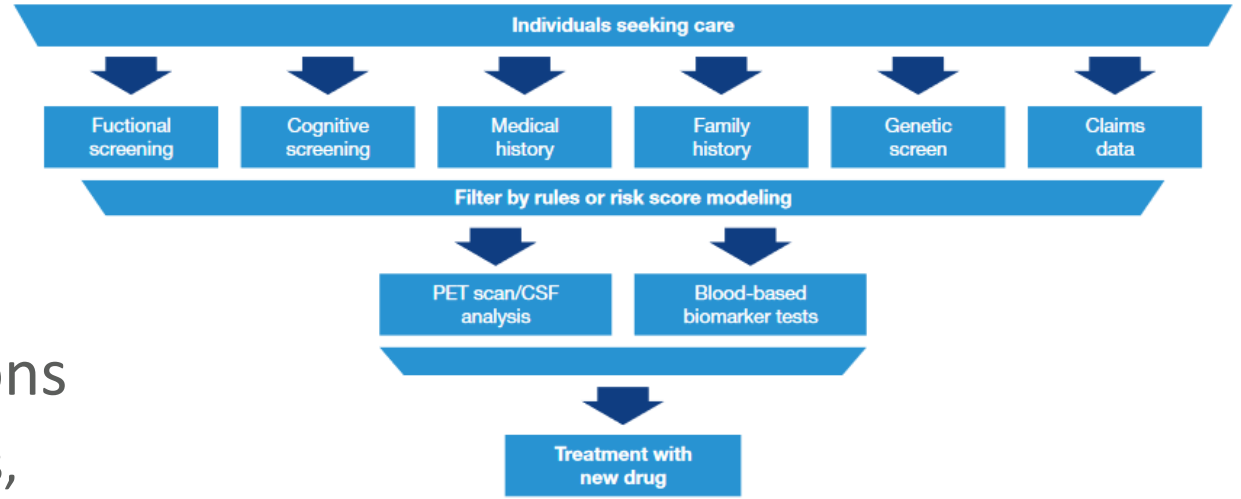
February 2020 issue brief overview

- Following expert workshop, Duke-Margolis developed an issue brief to capture critical discussion points
- This issue brief covers:
  - Potential therapies and impact on patient outcomes
  - Payment models that may be suited for reimbursement of these new therapies
  - Needed next steps to prepare for anticipated treatments and implementation of payment models

Potential therapies and patient impact

- The issue brief addresses potential screening process for access to therapeutics
  - Including areas of potential risk
- Examples of who might fall into pre-symptomatic and symptomatic populations
  - Generalize about age range, cognitive scores, healthcare-seeking behaviors
  - Consider conditions that might restrict treatment access

Figure 1. Potential pathway for diagnosis and treatment of early-stage Alzheimer's disease



Payment models to mitigate financial risk

- Uncertainties may lead to challenges in coverage and reimbursement of drugs
  - Questions about realization of downstream benefits in heterogeneous real-world populations
  - Traditional payment may limit coverage and access, reduce opportunities to learn after approval
- Reimbursement linked to available and emerging evidence by patient group may help address uncertainties
  - Would encourage evaluation of real-world patient outcomes, enabling broader access
  - Could mitigate some of the financial uncertainties associated with payment and value

Payment models that may be considered

Potential payment models		
Payment method	**Definition**	**Advantages to use**
Value-adjusted evidence-based pricing	Pricing based on existing evidence with potential for adjustment	Requires limited infrastructure to implement; May be relatively less complicated to monitor arrangements
Coverage with evidence development	Payment is linked to addressing unresolved evidence questions.	May be useful for uncertainty about treatment benefits in the real world; Conditioning payment on post-market data collection reduces payer risk while maintaining access
Outcomes-based payment	Links payment for product to performance in a patient/population	Final payment is based on evidence collected over time; Potential to mitigate financial risks associated with expanded coverage; Could improve understanding of the drug's impacts in a patient/population
Subscription payment	Product access for a recurring payment that is linked to product performance in target population	Allow for broader access at a potentially lower price; Payment may be adjusted or rebated based on outcomes; Would require tracking the health of a population over time.

Implementation challenges for new payment models

- Time horizon for tracking and treatment
- Consensus/standardization of outcomes measures
- Data collection and patient tracking
  - Currently no consistent baseline measures
  - Difficult to extract relevant data
  - Interoperability issues if patient switches provider/payer

Facilitating payment reform through improved use of data

- Data platform could better capture outcomes, and data sources may include:
  - Cognitive screening and biomarker test results
  - Comprehensive notes from provider visits
  - Health care utilization metrics
  - Patient- and caregiver- reported outcomes
- Better data collection also needed in primary care, prior to diagnosis
  - Identify potential patients sooner
  - Have baseline data on cognition
- Potential need for new EHR functions to capture unstructured data and enable all pertinent information to be centralized

Proposed next steps - payers

- Understand the evidentiary needs of payers and other stakeholders
  - What type of evidence is most useful for coverage decisions?
  - What outcomes need to be achieved for coverage and reimbursement?
  - What are the tools needed to evaluate the available evidence against uncertainty?
- Identify components of alternative or value-based payment models that could be applied to payment for new AD drugs

Proposed next steps - infrastructure

- Identify infrastructure needed to implement payment reform mechanisms
- Explore approaches for incorporating data collection into clinical practice
- Assessment of the changing data needs as the disease progresses

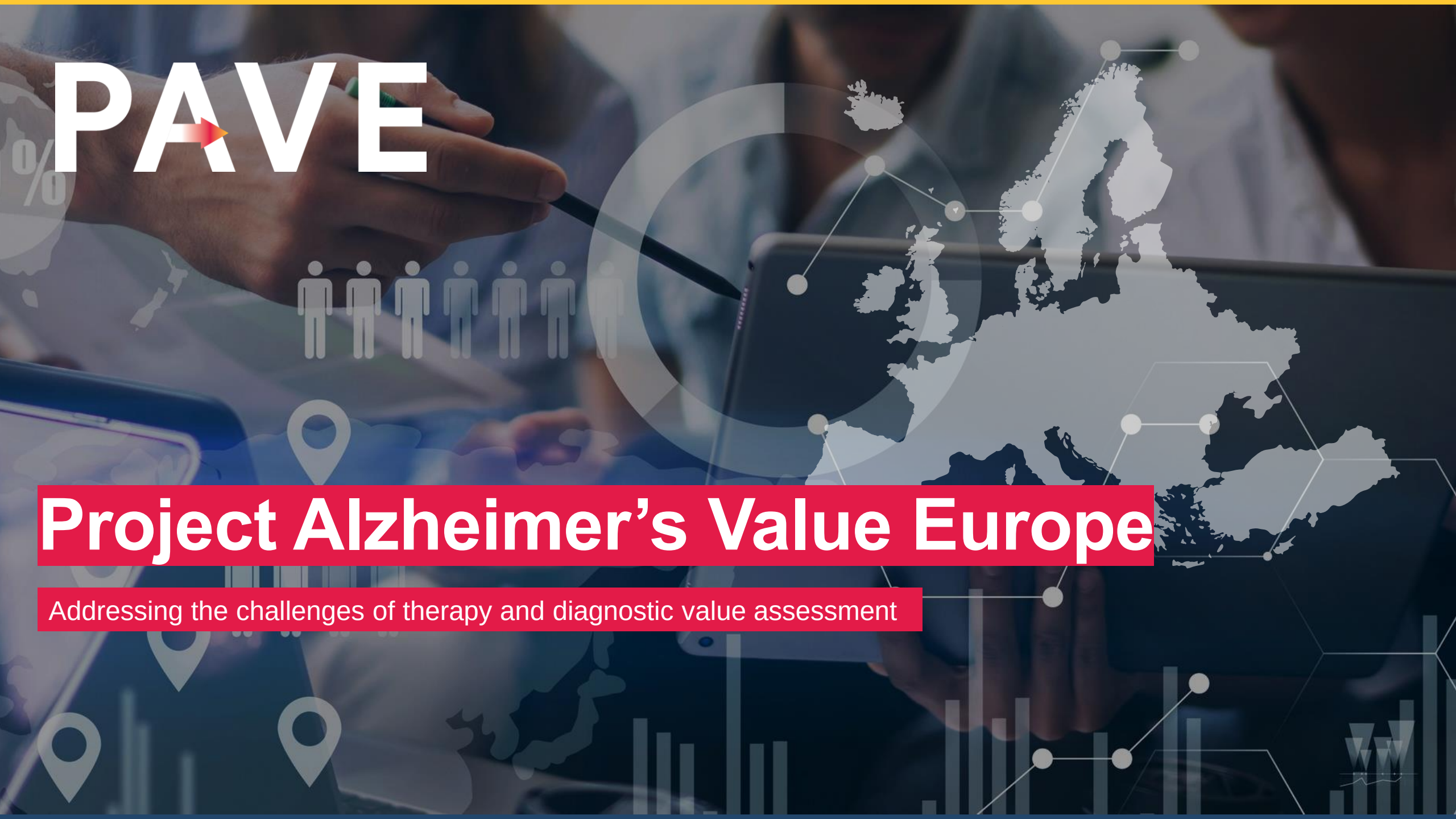
Discussants

- Phyllis Ferrell, Eli Lilly & Co.
- Lydia Lanman, F. Hoffman-La Roche

PAVE

Project Alzheimer's Value Europe

Addressing the challenges of therapy and diagnostic value assessment



Project Alzheimer's Value Europe

PAVE

PAVE is developing solutions to the challenges related to value assessment of and funding for emerging Alzheimer's therapies and diagnostics. PAVE is a forum for increased collaboration and understanding between key stakeholders in the Alzheimer's ecosystem within Europe, including regulators, bodies responsible for health technology assessment, payers, clinicians, patient advocates, and industry members.

PAVE Goals

1. **To educate policymakers, payers, and other influencers in key European countries on the current challenges related to assessing value in Alzheimer's disease; and,**

2. **To work together with European payers and policymakers to develop solutions related to the value assessment of, and funding / financing for future Alzheimer's disease therapies and diagnostics.**

2020 Projects

Drive Use of Registries

- Align on the ideal set of data elements collected at national and regional levels in disease registries to facilitate, share, and compare insights into how the health care process, evaluation and diagnosis of Alzheimer's disease is occurring. Understand the "best practices" in countries where registries are the strongest.

Address Payment and Access

- Outline potential new, innovative mechanisms for funding, financing and payment to support access and effective use of new treatments for Alzheimer's disease.

Core Elements for Measurement

- Identify and catalogue countries with approaches to health technology assessment (HTA) that take a broad view of the direct and indirect impact when evaluating innovative treatments and diagnostics.

Improve Understanding of Epidemiology and Impact

- Generate an updated, high-level review epidemiological literature to clarify what currently defines and quantifies dementia and Alzheimer's disease with the end goal of pinpointing eligible populations for treatment. The review would aim to help outline budget and resource impacts of diagnosing and treating Alzheimer's disease while providing common reference points for stakeholders beyond the general epidemiology of Alzheimer's disease.

PAVE Members

Driss Berdaï
Member, Transparency Commission, France

Annie Chicoye
Health Economist, Science Po Paris

Daniel DiGiusto
Global Integration Strategy Leader, F. Hoffmann-La Roche

Alison Evans
Head of Policy and Impact, Alzheimer's Research UK

Lutz Froelich
Professors & Head of Department of Geriatric Psychiatry, University of Heidelberg

Jean Georges
Executive Director, Alzheimer's Europe

Anders Gustavsson
Partner, Quantify Research

Niklas Hedberg
Chief Pharmacists, TLV

Geoff Huggins
Director of Health and Social Care Integrations, Scottish Ministry of Health

Pall Jonsson
Associate Director, Research and Development, NICE

Hulbert Kooljman
Head of Drug Pricing, Reimbursement, and Financial Arrangements, Ministry of Health Netherlands

Lydia Lanman
Senior Global Access Policy Leaders, F. Hoffmann-La Roche

Gerd Larfars
President of the Drug and Therapeutic Committee of the Stockholm County Council

Chris Lynch
Deputy CEO & Director of Policy, Communications &Publications, Alzheimer's Disease International

Jose Luis Molinuevo Guix
Hospital Clinic of Barcelona

Caridad Pontes
Lead for Pharmacotherapeutic Harmonization, Catalan Health Service

Michael Schlander
Professor of Health Economics, University of Heidelberg

Anja Schiel
Senior Advisor, Norwegian Medicine Agency

Nominations for membership are being accepted

Connect with Us

Contact

Lydian Lanman
Senior Global Access Policy Leader
Global Access Policy
Hoffman-La Roche
lydia.lanman@roche.com

info@PAVEurope.com
PAVEurope.com

Questions or comments from audience

Closing remarks

Thank you for your time!

For further questions or additional information, please contact Monika Schneider at monika.schneider@duke.edu