

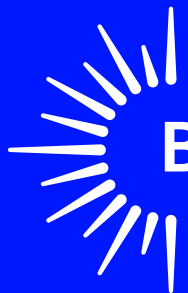
# USPSTF T1D Early Detection Campaign

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Breakthrough T1D

7<sup>th</sup> Annual Diabetes Screening Symposium

November 15, 2024



**Breakthrough T1D™**

Formerly JDRF



# Disclosure

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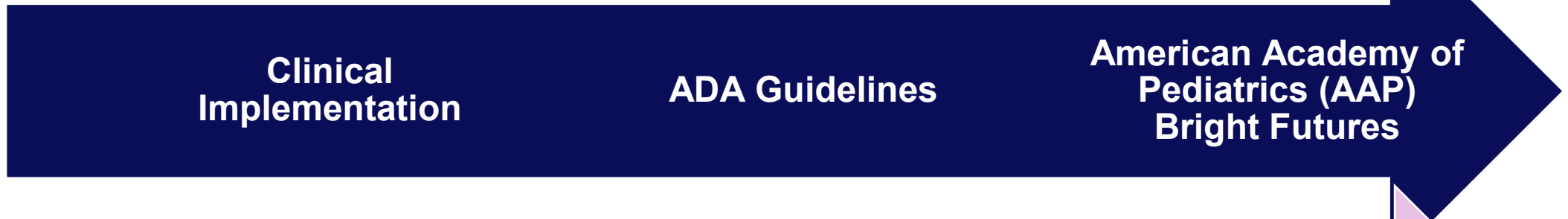
No conflicts of interest

# Our Vision to Expand T1D Early Detection

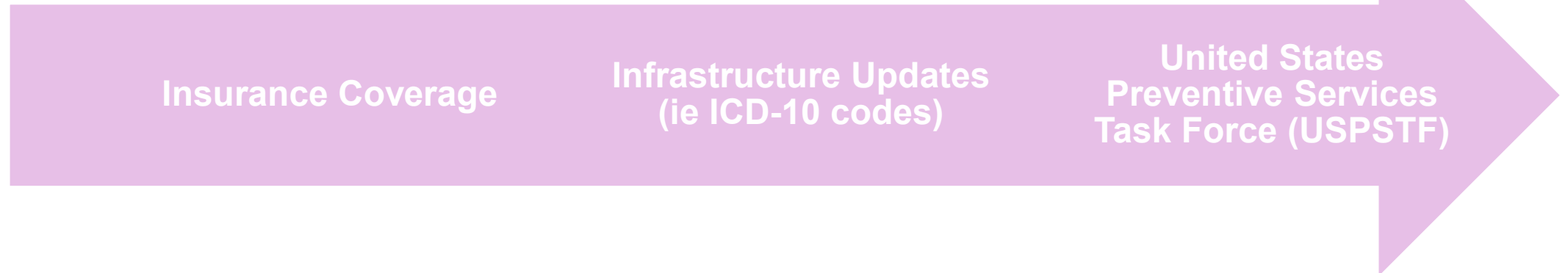
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**RESEARCH**

## Clinical Track



## Policy Track



# Breakthrough T1D's Early Detection USPSTF Campaign

# United States Preventive Services Task Force (USPSTF) Impact & Alignment w/Breakthrough T1D Vision

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## Impact of USPSTF Positive Recommendation

- USPSTF recommendations are gold standard for preventive services
- Federal law requires Medicare, Medicaid, and commercial health plans to cover the service
- Service must be free for patients
- Data shows increased utilization of service following recommendation

## Breakthrough T1D Vision

- Elevated knowledge of T1D early detection and cures therapies
- Screening routine for all people
- Broad coverage of screening and cures therapies by government/commercial payers; affordable for all

# Experts Recommend Submitting T1D Early Detection Nomination With a Focus on Children with Family History

A T1D screening recommendation is within scope for USPSTF; experts suggested that although it is unlikely to receive a Grade A recommendation, it could receive a Grade B. Under the ACA Grade B recommendations must be covered without cost sharing.

Experts recommended that Breakthrough T1D submit the nomination for a T1D recommendation as soon as possible, even as additional evidence generation activities are underway.

The strongest evidence for a T1D recommendation is in children with family history, especially since children are a priority for the USPSTF.

Avalere's scan of evidence mirrored the USPSTF process closely and will position T1D early detection for a nomination.

# T1D Early Detection USPSTF Campaign

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## **Campaign Description**

- Breakthrough T1D will lead an effort to secure a positive USPSTF recommendation for T1D Early Detection
- Effort will include key stakeholders (ie patient advocacy groups, clinical groups, & individual KOLs)

## **Our Commitment**

- Continue T1D Early Detection activities
  - Ongoing research funding
  - Investments to expand clinical adoption
  - Advocacy and public awareness
- Address data gaps through research funding

# USPSTF Background



# Who Is The USPSTF & What Is Their Mandate?

The Task Force, consisting of a panel of 16 experts appointed by Secretary of HHS, collaborates with four groups including the Agency for Healthcare Research and Quality (AHRQ), Evidence-based Practice Center (EPC), and other partners to form evidence-based recommendations on the use of preventive services and drugs.

## USPSTF Recommending Groups

- **Task Force:** selects topics for review, approves the analytical framework, and grades available evidence.
- **AHRQ:** provides research and technical support and coordinates the dissemination of the recommendation.
- **EPCs:** conducts systematic reviews of specific questions and evidence.
- **Partners:** comment, as invited, on draft research plans, evidence reviews, and recommendation statements.
- **Public:** nominates new task force members and provides public comments on certain recommendation materials

## USPSTF Meeting Process

- The Task Force meets three times a year (March, July, November)
- Meeting activities include:
  - Devise topic portfolio and prioritize topics
  - Discuss topic work plans, and key questions for evidence review
  - Review draft EPC evidence reports
  - Vote on variations of the USPSTF draft recommendation statement

## USPSTF Recommendation Scope

- USPSTF makes recommendations on primary or secondary preventive services that can be provided in or referred to the primary care setting
  - **Primary prevention:** Preventive services that aim to **avoid the development of disease**
  - **Secondary prevention:** Preventive service that aim to **identify and treat an existing disease** before it results in significant symptoms

# Why USPSTF for T1D Early Detection?

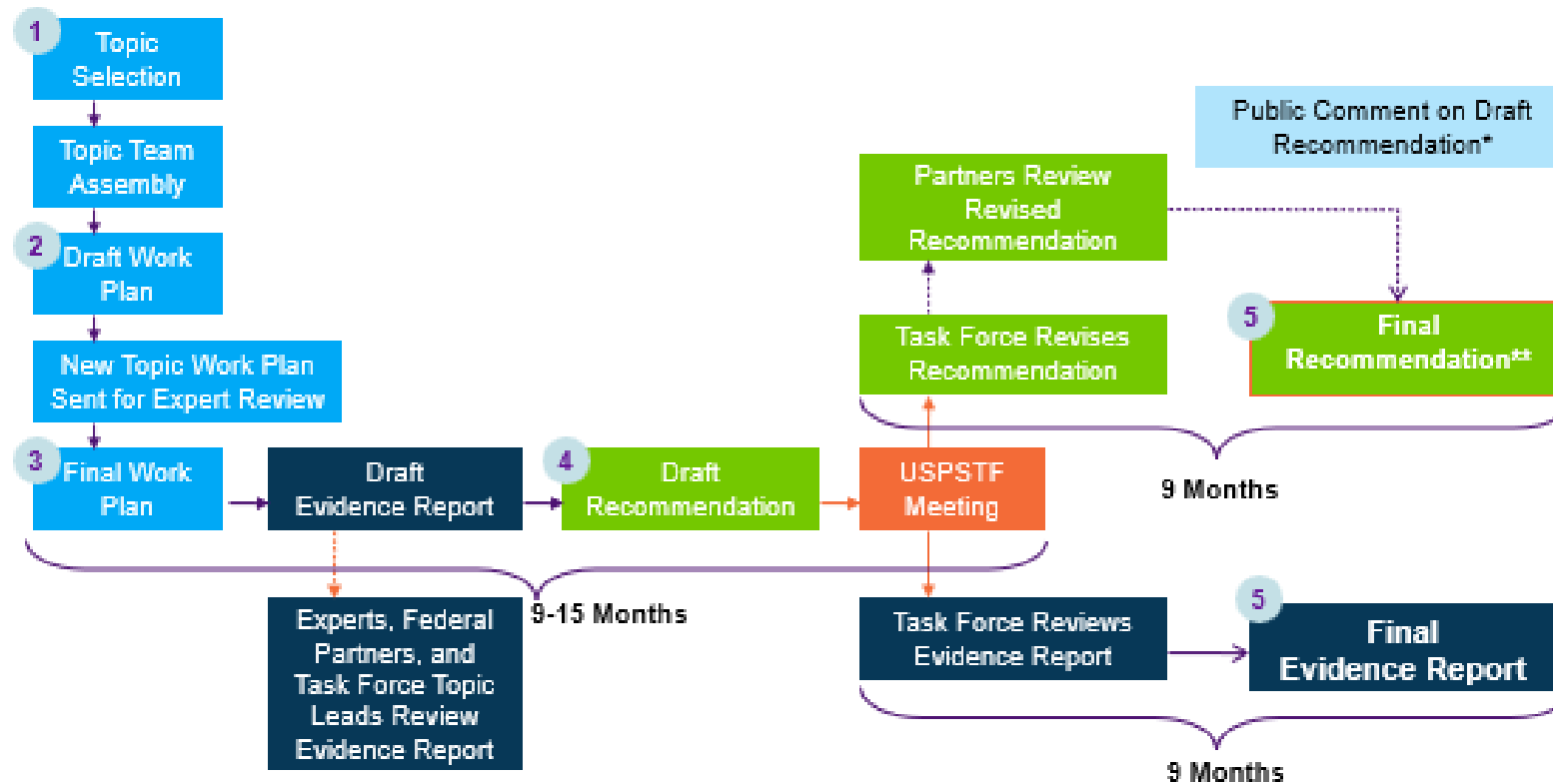
## Impact of USPSTF Grade A or Grade B Recommendation

- USPSTF recommendations are gold standard for preventive services
- Federal law requires Medicare, Medicaid, and commercial health plans to cover the service
- Service must be free for patients
- Data shows increased utilization of service following recommendation

## USPSTF Grading System

Grade	Definition
Grade A	<b>The USPSTF recommends the service.</b> There is high certainty that the net benefit is substantial.
Grade B	<b>The USPSTF recommends the service.</b> There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.
Grade C	<b>Clinicians may provide this service to selected patients</b> depending on individual circumstances. However, for most individuals without signs or symptoms there is likely to be only a small benefit from this service.
Grade D	<b>The USPSTF recommends against the service.</b> There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.
Grade I Statement	<b>The USPSTF concludes that the current evidence is insufficient</b> to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

# USPSTF Makes Recommendations Through an Established Public Process



# USPSTF Process

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## **1 or 2 New Topics Selected for the Agenda Annually**

- USPSTF determines which topics to address based on relevance, potential for new evidence, and need for updated recommendations
- Topics may be nominated multiple times or stay on list as a priority or several years

## **Evidence Review**

- For each topic, the USPSTF commissions a systematic review of the available evidence. This review is typically conducted by independent Evidence-Based Practice Centers (EPCs) under contract with the Agency for Healthcare Research and Quality (AHRQ)
- The evidence is assessed for quality, applicability, and the balance of benefits and harms. The review focuses on clinical outcomes, effectiveness, and the impact on different populations

## **Draft Recommendations**

- Draft recommendations developed and published which are evidence-based and consider the balance of benefits versus harms of the preventive service
- Draft recommendations are published for public comment. Healthcare professionals, organizations, and the general public can provide feedback, which is reviewed and considered by the USPSTF

## **Final Recommendations**

- After reviewing public comments and making any revisions, recommendations are finalized. These are then published in the form of a recommendation statement, which includes a summary of the evidence, the rationale for the recommendation, and any specific guidelines or suggestions

# Our Ask? Join the Campaign and Support T1D Screening Application

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- Join virtual campaign kick-off on January 14, 2025
- Participate in model-application consensus building
- Consider submitting a T1D early detection USPSTF application
- Join efforts to respond to USPSTF feedback

**Sign-up to join & learn more at [breakthrough1d.org/advocacy](https://breakthrough1d.org/advocacy) or email [yomer@breakthrough1d.org](mailto:yomer@breakthrough1d.org)**