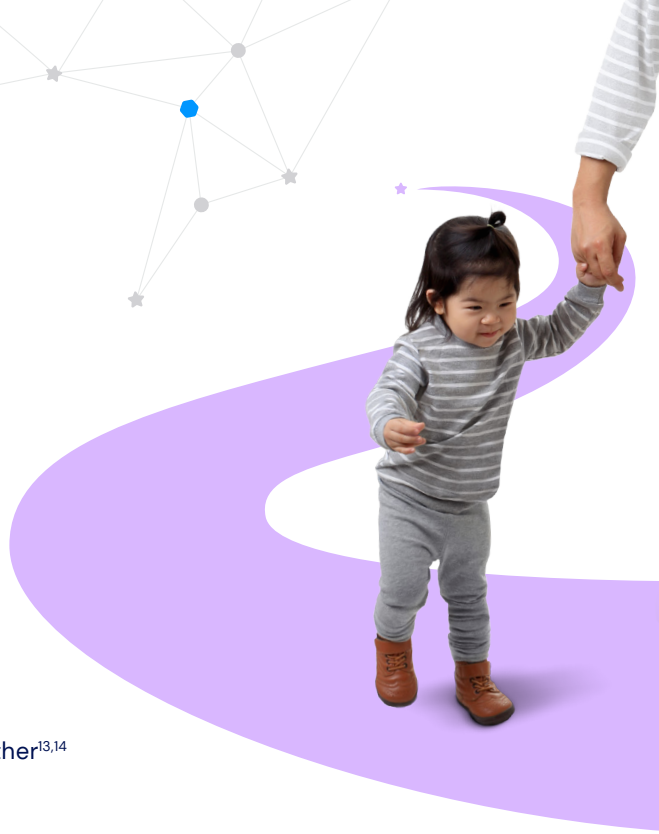
canvas Dx | Because Knowing is the First Step.

Early autism diagnosis and intervention — an opportunity for improved outcomes

Early diagnosis and intervention present a unique opportunity for children with autism spectrum disorder (ASD) to achieve optimal outcomes. But for the last 20 years, the average age of diagnosis has remained unchanged at **4 years and 3 months** — an **average delay of 3 years** between parental concern and a formal ASD diagnosis.[1–10]



Long wait times — A shortage of specialists and time-intensive evaluations result in long wait times for diagnostic appointments, causing substantial delays in diagnosis[11,12]

Lack of access — Children who are non-white, female, from rural areas or from disadvantaged socioeconomic backgrounds are often diagnosed later than the average diagnosis or missed altogether[13,14]

Delayed referrals — Because there is no standard diagnostic process for ASD and there are multiple types of specialists for referral, there is no clear pathway for PCPs[13,15]

Why Canvas Dx?

- Canvas Dx uses an AI-driven algorithm that combines 3 separate, user-friendly device inputs to aid primary care physicians (PCPs) in diagnosing ASD in young children. By helping PCPs diagnose or rule out ASD remotely or in person, Canvas Dx **may allow for more efficient specialty referrals — all within a critical neurodevelopmental window** for children at risk of developmental delay[16,17–19]
- In the pivotal study, the accuracy of Canvas Dx was assessed in comparison to the standard diagnostic approach (specialist evaluation and diagnosis) in a **multisite, prospective, double-blinded, active comparator cohort study**. The study included **425 children, aged 18–72 months, with parental or PCP concern for developmental delay**[16]
- Canvas Dx met primary endpoints with a Negative Predictive Value (NPV) of 98.3% and a Positive Predictive Value (PPV) of 80.8% and provided a "determinate result" (either positive or negative for ASD) 31.8% of the time[16]

Prescription and Dispensing of Canvas Dx

- Canvas Dx Rx form is sent to Orsini Specialty Pharmacy by FAX (see writeable PDF on CanvasDx.com)
- Orsini conducts benefit investigation and bills insurance company, subject to any prior authorization (PA) requirements
- Orsini dispenses Canvas Dx unique access code to parent/caregiver by email

After Canvas Dx is dispensed

- The parent/caregiver downloads Canvas Dx Caregiver App, enters access code and sets a password, completes caregiver questionnaire and records and uploads two videos*
- The healthcare provider completes a questionnaire through the Canvas Dx HCP Portal**
- Canvas Dx report is provided to the prescribing physician

* Cognoa Connect customer support team assists caregivers with any technical or product support needed in downloading, accessing, and using the Canvas Dx Caregiver App

** One of Canvas Dx's device inputs is a 13-15 item age-dependent health care provider (HCP) questionnaire collected via a health care provider portal. Cognoa has contracted with a pediatric care provider to offer the option to have a qualified HCP complete the HCP questionnaire via a video visit with the caregiver and child, with the goal of allowing for a streamlined experience. Alternatively, the prescribing physician can complete the questionnaire

How Canvas Dx works

The Canvas Dx algorithm evaluates all 3 inputs, generating a device report that the PCP utilizes in combination with their clinical judgement[16]

A parent/caregiver questionnaire that asks about the child's behavior and development collected via a parent/caregiver facing app[16]

A questionnaire completed by a video analyst who reviews two videos of the child recorded by the parents/caregivers[16]

An HCP questionnaire completed by a physician who meets with the child and a parent/caregiver, collected via a health care provider portal[16]*

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Cognoa is a pediatric behavioral health company developing diagnostic and therapeutic solutions with the goals of enabling equitable access to care and improving the lives and outcomes of children and families living with behavioral health conditions, starting with autism.

Cognoa.com

cognoa connect

Cognoa Connect is Cognoa's customer service team dedicated to supporting Canvas Dx. Whether you're a concerned parent or caregiver or a healthcare provider, Cognoa Connect aims to get you the answers you need to successfully prescribe or use Canvas Dx.

CognoaConnect.com

canvas Dx

For more information, contact your sales representative or visit **CanvasDx.com**

Indications for Use

Canvas Dx is intended for use by healthcare providers as an aid in the diagnosis of Autism Spectrum Disorder (ASD) for patients ages 18 months through 72 months who are at risk for developmental delay based on concerns of a parent, caregiver, or healthcare provider.

The device is not intended for use as a stand-alone diagnostic device but as an adjunct to the diagnostic process. The device is for prescription use only (Rx only).

Contraindications

There are no contraindications to using Canvas Dx.

Precautions, Warnings

The Device is intended for use by healthcare professionals trained and qualified to interpret the results of a behavioral assessment examination and to diagnose ASD.

The Device is intended for use in conjunction with patient history, clinical observations, and other clinical evidence the HCP determines are necessary before making clinical decisions. For instance, additional standardized testing may be sought to confirm the Device output, especially when the Device result is not Positive or Negative for ASD.

Canvas Dx is intended for patients with caregivers who have functional English capability (8th grade reading level or above) and have access to a compatible smartphone with an internet connection in the home environment.

The Device may give unreliable results if used in patients with other conditions that would have excluded them from the clinical study. Among those conditions are the following:

- Suspected auditory or visual hallucinations or with prior diagnosis of childhood onset schizophrenia.
- Known deafness or blindness.
- Known physical impairment affecting their ability to use their hands.
- Major dysmorphic features or prenatal exposure to teratogens such as fetal alcohol syndrome.
- History or diagnosis of genetic conditions (such as Rett syndrome or Fragile X).
- Microcephaly.
- History or prior diagnosis of epilepsy or seizures.
- History of or suspected neglect.
- History of brain defect injury or insult requiring interventions such as surgery or chronic medication.

The Device evaluation should be completed within 60 days of the time it is prescribed because neurodevelopmental milestones change rapidly in the indicated age group.

References

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