



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA  
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 01/03/23  
LAST REVIEW DATE: 09/03/24  
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## DIGITAL HEALTH TECHNOLOGIES: DIAGNOSTIC APPLICATIONS

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Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.



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## **DIGITAL HEALTH TECHNOLOGIES: DIAGNOSTIC APPLICATIONS**

### **Description:**

Autism spectrum disorder (ASD) is a biologically based neurodevelopment disorder characterized by persistent deficits in social communication and social interaction and restricted, repetitive patterns of behavior, interests, and activities. ASD can range from mild social impairment to severely impaired functioning: as many as half of individuals with autism are non-verbal and have symptoms that may include debilitating intellectual disabilities, inability to change routines, and severe sensory reactions.

Diagnosis of ASD in the United States generally occurs in two steps: developmental screening followed by comprehensive diagnostic evaluation if screened positive.

Digital health technologies is a broad term that includes categories such as mobile health, health information technology, wearable devices, telehealth and telemedicine, and personalized medicine. These technologies span a wide range of uses, from applications in general wellness to applications as medical devices, and include technologies intended for use as a medical product, as a companion diagnostic, or as an adjunct to other medical products (devices, drugs, and biologics).

This policy includes only those digital technologies that are intended to be used for diagnostic application (detecting presence or absence of a condition, the risk of developing a condition in the future, or treatment response [beneficial or adverse]) and meet the following 3 criterion:

- Must meet the definition of "software as a medical device" which states that software is intended to be used for a medical purpose, without being part of a hardware medical device or software that stores or transmits medical information.
- Must have received marketing clearance or approval by the U.S. Food and Drug Administration either through the *de novo* premarket process or 510(k) process or pre-market approval and
- Must be prescribed by a health care provider.

The Canvas Dx (formerly known as Cognoa App) is a prescription diagnostic aid to health care professionals considering the diagnosis of ASD in individuals 18 months through 72 months of age at risk for developmental delay. Canvas Dx incorporates 3 separate inputs. The individual's caregiver uses a smartphone application to fill out a caregiver questionnaire which asks about the child's behavior and development. The individual's caregiver also uses the smartphone application to make video recordings of behavior at home. A lightly trained video analyst reviews these videos of the child recorded by the parent/caregiver and completes a questionnaire. Finally, a health care professional meets with the child and a parent/caregiver and completes an online questionnaire via a health care provider portal. Canvas Dx utilizes a machine-learning algorithm that receives the 3 independent inputs and produces results.

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### Criteria:

- Prescription digital health technologies for diagnostic application as a diagnostic aid for autism spectrum disorder that have received clearance for marketing by the U.S. Food and Drug Administration are considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
  5. Insufficient evidence to support improvement outside the investigational setting

These applications include, *but are not limited to*:

- Canvas Dx

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### Resources:

Literature reviewed 09/03/24. We do not include marketing materials, poster boards and non-published literature in our review

Resources prior to 10/03/23 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. Abbas H, Garberson F, Liu-Mayo S, Glover E, Wall DP. Multi-modular AI Approach to Streamline Autism Diagnosis in Young Children. *Sci Rep*. Mar 19 2020;10(1):5014. doi:10.1038/s41598-020-61213-w
2. American Academy of Pediatrics. Autism Spectrum Disorder: Links to Commonly Used Screening Instruments and Tools (AAP Toolkits). Accessed May 17, 2024. <https://publications.aap.org/toolkits/pages/asd-screening-tools>
3. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)*. 5th ed. American Psychiatric Association; 2013.
4. Canvas Dx Website. Accessed May 17, 2024. <https://canvasdx.com/>
5. Dawson G, Bernier R. A quarter century of progress on the early detection and treatment of autism spectrum disorder. *Dev Psychopathol*. Nov 2013;25(4 Pt 2):1455-72. doi:10.1017/S0954579413000710

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6. Dawson G, Rogers S, Munson J, et al. Randomized, controlled trial of an intervention for toddlers with autism: the Early Start Denver Model. *Pediatrics*. Jan 2010;125(1):e17-23. doi:10.1542/peds.2009-0958
7. Hertz-Picciotto I, Delwiche L. The rise in autism and the role of age at diagnosis. *Epidemiology*. Jan 2009;20(1):84-90. doi:10.1097/EDE.0b013e3181902d15
8. Hyman SL, Levy SE, Myers SM, Council On Children With Disabilities SOD, Behavioral P. Identification, Evaluation, and Management of Children With Autism Spectrum Disorder. *Pediatrics*. Jan 2020;145(1)doi:10.1542/peds.2019-3447
9. International Medical Device Regulators Forum. Software as a Medical Device (SaMD): Key Definitions. 2013. Accessed May 17, 2024. <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf>.
10. Kleinman JM, Ventola PE, Pandey J, et al. Diagnostic stability in very young children with autism spectrum disorders. *J Autism Dev Disord*. Apr 2008;38(4):606-15. doi:10.1007/s10803-007-0427-8
11. Leigh JP, Grosse SD, Cassady D, Melnikow J, Hertz-Picciotto I. Spending by California's Department of Developmental Services for Persons with Autism across Demographic and Expenditure Categories. *PLoS One*. 2016;11(3):e0151970. doi:10.1371/journal.pone.0151970
12. Lipkin PH, Macias MM, Council On Children With Disabilities SOD, Behavioral P. Promoting Optimal Development: Identifying Infants and Young Children With Developmental Disorders Through Developmental Surveillance and Screening. *Pediatrics*. Jan 2020;145(1)doi:10.1542/peds.2019-3449
13. Maenner MJ, Shaw KA, Bakian AV, et al. Prevalence and Characteristics of Autism Spectrum Disorder Among Children Aged 8 Years - Autism and Developmental Disabilities Monitoring Network, 11 Sites, United States, 2018. *MMWR Surveill Summ*. Dec 3 2021;70(11):1-16. doi:10.15585/mmwr.ss7011a1
14. Megerian JT, Dey S, Melmed RD, et al. Evaluation of an artificial intelligence-based medical device for diagnosis of autism spectrum disorder. *NPJ Digit Med*. May 5 2022;5(1):57. doi:10.1038/s41746-022-00598-6
15. National Institute for Health and Care Excellence (NICE). Evidence standards framework for digital health technologies. 2021. Accessed May 17, 2024. <http://www.nice.org.uk/corporate/ecdf7/chapter/section-a-evidence-for-effectiveness-standards>
16. Randall M, Egberts KJ, Samtani A, et al. Diagnostic tests for autism spectrum disorder (ASD) in preschool children. *Cochrane Database Syst Rev*. Jul 24 2018;7(7):CD009044. doi:10.1002/14651858.CD009044.pub2



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- 17. Siu AL, Force USPST, Bibbins-Domingo K, et al. Screening for Autism Spectrum Disorder in Young Children: US Preventive Services Task Force Recommendation Statement. *JAMA*. Feb 16 2016;315(7):691-6. doi:10.1001/jama.2016.0018
- 18. Volkmar F, Siegel M, Woodbury-Smith M, et al. Practice parameter for the assessment and treatment of children and adolescents with autism spectrum disorder. *J Am Acad Child Adolesc Psychiatry*. Feb 2014;53(2):237-57. doi:10.1016/j.jaac.2013.10.013
- 19. Zwaigenbaum L, Bauman ML, Choueiri R, et al. Early Intervention for Children With Autism Spectrum Disorder Under 3 Years of Age: Recommendations for Practice and Research. *Pediatrics*. Oct 2015;136 Suppl 1(Suppl 1):S60-81. doi:10.1542/peds.2014-3667E
- 20. Zwaigenbaum L, Bryson S, Lord C, et al. Clinical assessment and management of toddlers with suspected autism spectrum disorder: insights from studies of high-risk infants. *Pediatrics*. May 2009;123(5):1383-91. doi:10.1542/peds.2008-1606

**Coding:**

CPT: No specific CPT code

<b><u>History:</u></b>	<b><u>Date:</u></b>	<b><u>Activity:</u></b>
Medical Policy Panel	09/03/24	Review with revisions
Medical Policy Panel	10/03/23	Review with no revisions
Medical Policy Panel	01/03/23	Approved guideline
Medical Director (Dr. Deering)	11/13/22	Development

**Policy Revisions:**

09/03/24 Updated: Resources section



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### Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, [crc@azblue.com](mailto:crc@azblue.com). You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

### Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idíílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíílkidgo beehaz'ánii hólo díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.



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Multi-Language Interpreter Services:

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:

اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799 [تماس حاصل نمایید.]

Assyrian:

Blue Cross Blue Shield of Arizona ... 877-475-4799

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคุณ หรือคนที่คุณกำลังช่วยเหลือถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสมสิทธิ์ที่จะได้รับความช่วยเหลือและขอมลในภาษา ของคุณได้โดยไมมีค่าใช้จ่าย โปรดขอมล โทร 877-475-4799