



New York State Medicaid Evidence Based Benefit Review Advisory Committee

Thursday, November 21, 2024

10:00 a.m. – 3:30 p.m. (EDT)

90 Church Street, New York, NY 10007 – Meeting Room 4AB

Meeting Summary

Attendees
<p>Committee Members: Edmund Altone, Victor M. Badner, Elisabeth Benjamin, Ronald Braithwaite, Katherine Breslin, Douglas DeLong, James De Meo, Marie-Carmel Garçon, Sanjiv Shah, Thomas Smith, Joseph Truglio, Emily Leish, Warren Seigel, Jacob Wallace, Douglas Fish*, Nathan Graber**</p> <p>NYS DOH Staff: Shirley Belotte, Kate Bliss, Myla Harrison, Daniel Leifer, Melissa Miller, Suzette Sadio, Ismail Salihu, Trisha Schell-Guy, Thomas Sciortino, Christian Soto</p> <p>Center for Evidence-based Policy Staff: Jesse Baumgartner, Elizabeth Brown, Véronique Johnstone, Valerie King, Allison Leof, Laura Pavlech</p> <p>Public Comment: Joseph Perekupka, Chief Executive Officer of Freespira</p>

*Chair of the Committee

**Chair Designee

Welcome and Introductions	
Discussion	<p>Dr. Nathan Graber and Dr. Douglas Fish welcomed the Committee members.</p> <p>EBBRAC members present introduced themselves.</p> <p>Nathan Graber announced that there are no remaining vacancies on the EBBRAC. Dr. Jaare H, Weber, MD was appointed to fill the Assembly seat.</p> <p>Nathan Graber reviewed evidence to decision making frameworks for committee consideration.</p> <p>Nathan Graber reported that coverage for collagen cross-linking for members with progressive keratoconus is still under review by the Department.</p>



	NYSDOH should be able to provide a detailed update for EBBRAC members at the next meeting.
Action Items and Decisions	None.
New York Department of Health Updates	
Discussion	<p>Trisha Schell-Guy provided NYSDOH updates. The department is working on implementing the 1115 health equity waiver. As part of the health-related social needs portion of the waiver, NYSDOH has established 9 regional social care networks. They will be responsible for building a network of providers to screen Medicaid members for social needs, provide navigation and deliver social care services. The department is also implementing workforce investments to achieve equity goals and developing a hospital global budget initiative to stabilize safety net hospitals.</p> <p>The department has submitted the state’s 2023-2025 quality strategy to CMS. This is required when a state utilizes a managed care delivery system.</p> <p>Elisabeth Benjamin asked about potential impacts of a new administration on the 1115 waiver. Trisha Schell-Guy noted that the current waiver is approved through March 31, 2027 by CMS. Elisabeth Benjamin noted that the state also received approval from CMS to offer continuous enrollment to Medicaid members from ages zero to 6 years, which Trisha Schell-Guy confirmed.</p>
Action Items and Decisions	None.
Public Comment and Presentations (if available)	
Discussion	Joseph Perekupka, Chief Executive Officer of Freespira, provided public comment.

Action Items and Decisions	<p>Elisabeth Benjamin requested that in the future any submissions of public comments be made available to the EBBRAC members through BoardVantage before the meeting.</p> <p>Nathan Graber agreed to post submissions received before the meeting to the BoardVantage prior to the meeting in the future. The summary statement that Joseph Perekupka submitted was loaded to BoardVantage for member consideration.</p>
Digital Health Technologies, Definitions, Regulatory Framework, and Considerations	
Discussion	<p>Elizabeth Brown presented an overview of how digital health technologies are defined, described how the US Food and Drug Administration (FDA) regulates the technologies, and provided information for EBBRAC members and NYSDOH staff to consider when deciding on coverage for these technologies.</p> <p>Committee discussion points included:</p> <ul style="list-style-type: none"> • The difference between health and wellness apps marketed directly to consumers and digital health technologies that are reviewed by the FDA • Whether or not consumers and clinicians understand the different FDA medical device pathways used to authorize or clear digital therapeutics for the market and how those regulatory frameworks compare to regulations of pharmaceuticals
Action Items and Decisions	None
Topic: Freespira	
Discussion	<p>Elizabeth Brown presented an overview of the evidence for Freespira as a treatment for panic disorder and posttraumatic stress disorder (PTSD), and a review of clinical practice guidelines and coverage policies from select private payers and state Medicaid programs. For full details see the report available on the EBBRAC website. The Committee was tasked with determining whether (a) there was sufficient high-quality evidence demonstrating the effectiveness of Freespira for individuals with panic disorder or PTSD; and (b) whether the evidence supported coverage of the treatment.</p>

	<p>Committee discussion points included:</p> <ul style="list-style-type: none"> • Questions about the placebo effect in studies of treatment for mental health conditions and whether the study design accounted for the placebo effect • Whether other completed and ongoing studies of the treatment might be published and whether the Committee could reconsider the treatment if further evidence was produced • Problems with access to psychotherapy services for Medicaid members and whether NYSDOH could analyze data to identify access issues • Whether MCOs could cover Freespira on their own. • Concerns that MCOs could use Freespira as part of a step therapy requirement that would bar Medicaid member access to other treatments. Trish Schell-Guy clarified that MCOs could not use a non-covered benefit as step-therapy to access a covered benefit such as psychotherapy. This would violate the MCO model contract. • Concerns about the evidence base required for FDA clearance of these technologies <p>NYSDOH put forward a recommendation for the committee’s consideration that “the DOH does not recommend pursuing NYS Medicaid coverage of the digital therapeutic Freespira for the treatment of panic disorder or PTSD at this time.” Thomas Smith made the motion to approve, Elisabeth Benjamin and Sanjiv Shah seconded the motion.</p> <p>The Committee amended the motion to read: “The Evidence Based Benefits Review Advisory Committee does not recommend pursuing New York State Medicaid coverage of the digital therapeutic ‘Freespira’ for the treatment of panic disorder or PTSD at this time.”</p>
<p>Action Items and Decisions</p>	<p>The Committee voted unanimously to approve the motion (16 yeas, 0 nays, 0 abstentions).</p>
<p>Topic: Canvas Dx</p>	
<p>Discussion</p>	<p>Elizabeth Brown presented an overview of the evidence for Canvas Dx as a diagnostic aid for autism spectrum disorder in young children and an overview of clinical practice guidelines and coverage policies from select private payers and state Medicaid programs related to Canvas Dx. For full</p>

details see the report available on the EBBRAC website. The Committee was tasked with determining whether (a) there was sufficient high-quality evidence demonstrating the effectiveness of Canvas Dx as a diagnostic aid for identifying autism spectrum disorder in young children; and (b) whether the evidence supported coverage of the treatment.

Committee discussion points included:

- The shortage of developmental pediatricians and other clinicians who can diagnose autism spectrum disorder which leads to long wait times for assessment and delays in accessing treatment
- Questions about the training provided to the non-experts who review the videos as part of the Canvas Dx process
- Concerns that Canvas Dx is a diagnostic *aid* and is not sufficient to make a definitive diagnosis of a condition; use of Canvas Dx may not eliminate the need for a comprehensive diagnostic assessment
- Concerns about access to early intervention, and that the current early intervention system is inadequate to provide services for all children who need them. There was recognition that coverage of Canvas Dx would not solve that problem
- Concerns about the machine learning algorithm used in Canvas Dx and evidence that the algorithm performs better with white male children and may exacerbate health equity considerations
- Comment that the use case for this test might be in excluding a diagnosis of autism spectrum disorder because of the high negative predictive value of the test
- Concerns about updates to software in digital health technologies and how changes to technology can be addressed by the EBBRAC

NYSDOH put forward a recommendation for the committee’s consideration that “NYSDOH does not recommend pursuing NY state Medicaid coverage of the digital therapeutic Canvas DX as a diagnostic aid for Autism Spectrum Disorder in young children at this time.”

Warren Seigel recommended removing the word “young.”

Douglas DeLong recommended removing the word “pursuing.”

The Committee amended the motion to read: “The Evidence Based Benefits Review Advisory Committee does not recommend New York State Medicaid coverage of the digital therapeutic “Canvas Dx” as a diagnostic aid for Autism Spectrum Disorder in children at this time.”

	Kate Breslin moved to approve the recommendation; Warren Seigel seconded the motion.
Action Items and Decisions	The Committee decided unanimously to approve the motion (16 yeas, 0 nays, 0 abstentions).
Final Comments	
Discussion	<p>NSYDOH proposed 2025 EBBRAC meeting dates:</p> <ul style="list-style-type: none"> • April 10, 2025 • July 24, 2025 • November 6, 2025 <p>Elisabeth Benjamin suggested that the November date may conflict with the annual SOMOS conference. Nathan Graber agreed to look into an alternative fall meeting date.</p> <p>Elisabeth Benjamin suggested that in the future lunch might be brought in or EBBRAC members could bring lunch so Committee members could continue to work over the lunch break. Nathan Graber agreed to look into lunch options.</p>
Action Items and Decisions	<p>Joseph Truglio moved to adjourn the meeting; Jacob Wallace seconded the motion.</p> <p>The motion was unanimously approved (16 yeas, 0 nays, 0 abstentions) and the meeting was adjourned.</p>