New York State Medicaid Evidence Based Benefit Review Advisory Committee

Thursday, July 23, 2026
10:30 a.m. – 3:30 p.m. (EDT)

Empire State Plaza, Concourse
Meeting Room # 6
Albany NY

Meeting Summary

Attendees
Committee Members Present: Edmund (Russ) Altone, Victor M. Badner, Ronald Braithwaite, Elisabeth Benjamin, Katherine Breslin, James De Meo, Marie-Carmel Garçon, Emily Leish, Peter Newell, Sanjiv Shah, Warren Seigel, Thomas Smith, Jacob Wallace (virtual), Kaare Weber, Deirdre Wheat, Nathan Graber* ***Committee Members Absent:*** *Douglas DeLong, Miranda Greiner, Joseph Truglio* **NY DOH Staff:** Khalil Alshaer, Shirley Belotte, Kate Bliss, Cristin Connor, Daniel Duffy, Nathan Graber, Michael Rinaldi, Suzette Sadio, Thomas Sciortino, Trisha Schell-Guy, Stacy Van Gelden **Center for Evidence-based Policy Staff:** Elizabeth Brown, Susan Connor (virtual), Hayley De Carolis, Jami Hoffman, Val King, Laura Pavlech, Susan Stuard **Public Comment:** None **Other:** None

*Chair of the Committee

Welcome and Introductions	
Discussion	Nathan Graber welcomed the Committee members, reviewed the role of the Evidence Based Benefit Review Advisory Committee (EBBRAC), and confirmed that the Committee had quorum to proceed.

	Nathan Graber noted that there are no public commenters planned but the public can contact the committee, review documents, or suggest topics via email or the EBBRAC website on NYS Medicaid's website. EBBRAC members and Center for Evidence-based Policy staff present introduced themselves. Nathan Graber introduced the NYSDOH staff supporting the Committee.
Action Items /Decisions	None
EBBRAC Bylaws Review	
Discussion	Nathan Graber reminded attendees that EBBRAC committee bylaws must be reviewed biannually and offered committee members the opportunity to suggest revisions or additions to bylaws. Elisabeth Benjamin requested delaying bylaw discussion until November's meeting.
Action Items/Decisions	There were no objections to discussing bylaws during November's meeting and Nathan Graber reminded members to send suggestions via email and NYSDOH staff will incorporate into bylaws.
New York Department of Health Updates	
Discussion	Kate Bliss presented updates from NYSDOH. For details, see posted slide deck. Topics discussed: • Draft primary care strategy domains • PCMH quality measures • Contingency management pilot Committee questions and discussion points included: • Why isn't All Payers Claims Database (APCD) data publicly shared? Wouldn't that help with primary care investment policy decisions (e.g., the Primary Care Investment Act)? o Kate Bliss shared that APCD is tracked internally but the primary care definition may not align with other sources.

	• Does NYSDOH weight PCMH quality measures based on impact to various outcomes? Certain measures may impact the population level or significantly affect quality of life but are considered equally to less effective measures. o Kate Bliss explained that early changes to PCMH quality measures have not made that consideration, but this should be considered a long-term program, and the department may be interested in thinking through this for future measures. o Nathan Graber emphasized that CHIP and Medicaid quality improvement strategy is foundation for other quality initiatives. As the department works to align all quality strategy work, they will revisit this comment about considering the varied impacts of certain measures. • What is the timeline for publicly sharing the quality strategy? o Kate Bliss shared it is being reviewed now, and she is hoping to send link to entire committee within the next few weeks.
Action Items /Decisions	Kate Bliss will consult with NYSDOH colleagues about sharing APCD data publicly and will update committee at next meeting. Kate Bliss will share quality strategy with committee members within a few weeks and welcomes comments from members.
Topic Introduction & Public Comment/Presentations	
Discussion	Nathan Graber began discussion by emphasizing the charge of today's meeting to evaluate an artificial intelligence (AI)-enabled device used to screen for, not diagnose, diabetic retinopathy. The device can be used for diagnosis, but that is not the scope of today's discussion. A question to keep in mind: is the evidence strong enough to support its use so that the state would establish a reimbursement mechanism for use? Nathan Graber also reminded the committee to review Boardvantage for questions that were submitted by committee members prior to the meeting as they were either addressed there or will be discussed during today's presentation. Committee questions and discussion points included: • Nathan Graber shared that approximately 1.5 million New York Medicaid members have diabetes and approximately 600,000 people are not adequately screened for diabetic retinopathy. These numbers are rough estimates. More detailed estimates would be done during the fiscal analysis process if a recommendation for coverage proceeds.

	• The HEDIS measure reports people with diabetes who have negative retinopathy screen during measurement year. That carries over to following year, so screening gets credit for 2 years. Did you consider that in report? o Nathan Graber said that would be explained in the report presentation but clarified the intent is to align with guidelines.
Action Items /Decisions	None
Topic: AI-Enabled Devices for Autonomous Screening for Diabetic Retinopathy	
Discussion	The Center for Evidence-based Policy's Elizabeth Brown presented an overview of the evidence for AI-enabled devices for autonomous screening for diabetic retinopathy, and a review of clinical practice guidelines and coverage policies from private insurers, state Medicaid programs, and Medicare. For full details, see the report available on the EBBRAC website. Committee questions and discussion points included: • What is the diabetic retinopathy screening policy for children or adolescents with diabetes? o Nathan Graber responded that the review is limited to adults 18 and over because this is the population for which the devices under review are currently FDA cleared. • Of the 600,000 Medicaid members with screening needs, how many are seeing doctors or are engaged in the health care system some other way o Nathan Graber responded that the 600,000 is a rough estimate based on claims data with diagnoses codes attached. So, they would have had to see a clinician. • Are there any ophthalmology-specific provider adequacy studies for Medicaid managed care plans; is there a problem with provider access o If this recommendation ends up driving more demand for ophthalmologists, it would be good to know we have the supply needed. o Nathan Graber responded that it's hard to comment on provider adequacy due to reporting definitions based on licensure requirements that do not always reflect total

	workforce. Plans are required to ensure network adequacy, and this is not an area that is frequently flagged as having low capacity. • Is the current expectation that 100% of patients with diabetes see an ophthalmologist; could this intervention potentially lower demand for ophthalmologists o A committee member clarified that screening can be done by an optometrist, you don't need an ophthalmologist for screening. o Another committee member responded that clinics with specialized fundus cameras send those images to an optometrist to read remotely and there has not been any issue with the timeliness of reading because of increased volume. o Center staff confirmed that these images are transmitted to a reading center and read remotely normally within a couple days to a week or 2. o Center staff explained that the remote reading screenings have been used to increase access for people in areas with a shortage of specialists and that clinicians reading the screenings are not necessarily ophthalmologists but are highly trained to read images for a range of retinal abnormalities (i.e., not only diabetic retinopathy). • There have been significant investment from some practices to purchase the fundus cameras and maybe for those providers, it may be a perfectly acceptable way to continue screening, as opposed to investing in new AI technology o Nathan Graber confirmed that there is a payment mechanism for the remote readings of these screenings done in primary care clinics, so what we are discussing today would be an alternative to current policy. • There seems to be many potential benefits of placing AI-enabled technology into primary care settings, especially for Medicaid members: why is it so difficult, however, in primary care to dilate eyes and get the maximum benefit from the machine rather than risking getting unreadable results without dilation o Center staff responded that while dilation is in the scope of primary care practice, it is not often done because of the time required, side effects from pupil dilation, and in-office workflow challenges. o The committee member appreciates the many barriers to pupil dilation, including transportation, childcare, time off

	work, but wondered how dilating in the primary care setting would give better quality images and therefore reduce the number of images that the AI-enabled devices cannot read. Other members shared how dilation impacts re-screening rates negatively, how primary care reimbursement is 20 minutes for an established patient and that time is not sufficient for pupil dilation. o A committee member proposed incentive payments attached to screening as potential solution to this concern. o Center staff clarified that FDA-cleared protocols for use of the devices do not include pupil dilation for all patients, only for those patients for whom the initial images are unreadable (i.e., reflex dilation in response to an unreadable result). • What is an example of risk-of-bias concerns for the reviewed studies; are the authors or researchers employed by the manufacturing company o Center staff responded that in all the studies, financial conflict of interest and author affiliation were major concerns. o The studies were mostly comparative observational studies where may introduce bias during group selection. o A committee member asked how you would randomize an intervention like this screening technology. o Center staff responded that you could do a clustered randomized trial. • Think about the trade-offs of applying risk of bias framework to prediction problems rather than causal questions and these studies are asking about effect of tool versus precision of tool o Center staff agreed and also shared it makes sense to think about who is selected to receive the treatment (autonomous AI screening) and who is not. o Another committee member responded that they have the same perspective and think bias may be overstated in this case. o The bias labels are more about these particular studies that report on clinical utility of tests under certain circumstances (e.g., dilation). o Center staff confirmed that results of these studies show that if you get a negative test, you can pretty much rely on that finding. • How to distinguish between products with high predictive value or negative predictive value from other products that have not been

	reviewed in forming a recommendation; how to remain agnostic to product names or manufacturers o Center staff clarified that, at present these are the only 3 products that have been cleared by the FDA, and these were authorized via 510(k) FDA pathway. • What is state's stance on which devices should be covered especially due to significant investment required for these machines and technology; will there be a return on their investment o Center staff acknowledged this concern and suggested this is something the state will need to consider. • Surprised at how useful these tests are for ruling out disease even without dilation; will coverage decision rely on the number of screenings that are readable, because there are significant difference between products (e.g., unreadable rate for one product is 12% and is 24% for the other) • Do study results on clinical utility (slides 78 - 80) suggest that the use of this device is a motivational tool to get individuals to follow up on their referrals and that patients listen to AI more often than they'll listen to their doctor o Center staff confirmed this is a potential interpretation of the results, although it may be the immediacy of the results than the use of AI itself. The Dow (2023) study results suggest that shorter time to screening results compared to human readings may improve patient follow-up with an ophthalmologist for patients with referrable findings. • Was Dow (2023) authored by the manufacture; any bias related to the financing of the study o One author reported 'other' relationship with Digital Diagnostics, the manufacturer of the AI device used in the study. o The study was funded in part by grants from the National Institutes of Health (NIH) and Stanford Diabetes Research Center. o Center staff identified that the other important finding in the Dow (2023) study was the ability to see a difference between people with more-than-mild disease. • Dow (2023) tracked follow-up visit to ophthalmology. Patients were allowed to choose their ophthalmologist. The study looked for evidence of follow-up in the Stanford Health Care system's electronic medical record (EMR). o Center staff clarified that in Dow (2023), patients were screened via tele-ophthalmology (images sent for reading by

	a human), AI-enabled device (IDx-DR, later renamed LumineticsCore), or if the images received an ungradable result from the AI device, they were sent to the human-based tele-ophthalmology workflow. o All patients received results via the EMR patient portal, a phone call, or a letter. Any patient with more-than-mild diabetic retinopathy or an ungradable result for the AI-Human (tele-ophthalmology) workflow received a phone call. Tele-ophthalmology results took up to 7 days while results from the AI device took up to 48 hours to be delivered to the patient (although, results were available almost immediately [within 5 minutes] with the AI device). A committee member speculated that if the results were available during the appointment that it could have increased referral to an ophthalmologist with an appointment being scheduled. • A committee member asked whether there were any data on a patient who receives an ungradable image on their first screening and what their results are in subsequent screenings with an AI-enabled device (not taken at time of initial screening); does readability change based on technique o Center staff explained they did not see any studies that measured this specifically, but did not see anything that said if a patient gets an unreadable initial screening with an AI-enabled device they can never be screened with the AI device again. • Another consideration would be workforce and who is available: a patient may be referred for another screen in 6 months instead of a year, if results are unreadable. • A committee member stated that if the images are ungradable that doesn't mean the patient has to be referred to an ophthalmologist, they can be referred to an optometrist. • A committee member noted that many people have conditions that make it difficult for even the best machine to evaluate eye; this must account for some percentage of the unreadable results and that needs to be considered when interpreting these results. • What percentage of the unreadable results are attributed to conditions that are unrelated to diabetes o Center staff confirmed that this was not reported in the studies identified for this report.

	• In reference to Medicare's coverage policy and reimbursement rate (slide 107), does this mean Medicare reimburses a higher rate for AI readings than a doctor o Dan Duffy (Deputy Bureau Director, Medical and Dental Policy) clarified that rates are clinic-based reimbursement and are based on a different reimbursement methodology. o Reimbursement for clinics is different because it's on a larger scale than a physician's office. o Similar to ambulatory patient group (APG) reimbursement methodology, clinics will have a higher payment rate than physician offices. o What New York State Medicaid would pay on these devices would be more for APG sites than Medicaid physician fee schedule. • Slide 109: 7 of 9 reviewed Medicaid agencies cover AI-enabled diabetic retinopathy analysis, based on coverage of CPT code 92229; why does Oregon not cover device o Center staff noted that Oregon reviewed this code 6 years ago and felt there was insufficient evidence of effectiveness at that time. Additional studies (including several studies in this report) have been published since that time. o A committee member noted we do not know if the 7 states that do cover the device reviewed the evidence or just added the CPT code for coverage. After the conclusion of the presentation, the Committee moved into discussion and the development of a recommendation. Kate Breslin asked Nathan Graber to remind the committee how this issue was identified as an EBBRAC topic. Nathan Graber explained the process for identifying appropriate topics for EBBRAC and their recent interest in AI-enabled technologies. Diabetic retinopathy was selected in consultation with the Center for Evidence-based Policy. November's EBBRAC meeting will discuss an AI-enabled devices for evaluating fractional flow reserve (FFR) CT for patients with coronary artery disease. The Center for Evidence-based Policy's Valerie King added that AI-enabled devices for diabetic retinopathy are 1 of 3 AI-enabled devices that have been assigned a permanent, instead of temporary, CPT code. Elisabeth Benjamin asked if the committee is aware of any interest from providers or community health centers in using this technology. Nathan Graber shared that the department did not hear of interest in this device

	during informal conversations prior to the EBBRAC meeting. The department has not measured provider interest. Sanjiv Shah asked if there is a sense of the preference or interest between standard of care versus tele-ophthalmology versus these AI-enabled devices. He asked how the department would handle clinics that have already significantly invested in the existing technology for tele-ophthalmology. Would the department's guidance be to switch to an AI-enabled device? Nathan Graber replied that today's recommendation will not be used to encourage any changes for practices with adequate screening rates. Based on what he has heard, Nathan Graber noted that the tele-ophthalmology option with human reading may be a better approach than the AI approach but suggested this may be a question for the Center of Evidence-based Policy to research. Sanjiv Shah said he would be interested to know if there is data on how many images are sent that are unreadable or ungradable. Elizabeth Brown from the Center for Evidence-based Policy replied that there is inadequate evidence to assess the follow-up rates after AI screening versus human screening. According to Elizabeth Brown, reviewed studies did not fully answer this question of clinical utility. Sanjiv Shah followed that practices could not add the AI technology onto existing fundus cameras. If practices have already purchased the tele-ophthalmology camera, are they able to switch from human readings to AI readings? Valerie King from the Center for Evidence-based Policy replied that this can be done in the European Union and United Kingdom, but not in the United States because the FDA cleared the devices for use with specific cameras. Edmund (Russ) Alton pointed out that, based on his understanding, in most cases, a positive diabetic retinopathy screen would result in a treatment recommendation for glucose and cholesterol monitoring and control. Only a fraction of the cases would require sophisticated treatment by an ophthalmologist. The solution, therefore, becomes a function of health promotion, working through various public health means to try and get people to their appointments. Elizabeth Brown offered to send a white paper from The Commonwealth Fund about integration of AI into community health centers. Elisabeth Benjamin said that would be helpful. Nathan Graber noted that federally

	qualified health centers (FQHCs) tend to have all services in 1 place, so optometry and sometimes ophthalmology are already at the same location. Nathan Graber asked if the committee had further discussion or if they'd like to start the recommendation development. Emily Leish summarized the preceding discussion: under the current standard of care, everybody should be referred to an ophthalmologist for diagnosis. This tool is most effective in ruling out the presence of diabetic retinopathy, so the potential employment of this tool would be to reduce the number of people who are referred to an ophthalmologist. Is that correct? Nathan Graber confirmed this was correct. Elisabeth Benjamin circled back to an earlier discussion point about whether network adequacy issues exist for ophthalmologists in NYS Medicaid. She noted that the Committee does not know if there is an issue with accessing an ophthalmologist or if there are long wait times for appointments. According to Elisabeth Benjamin, the Committee does not know if this recommendation is solving a problem that exists or not. On the other hand, if the Committee does not recommend, is it maintaining a barrier or burden for FQHCs that may have a large population of patients with diabetes? Elisabeth Benjamin asked which portion of this technology is already reimbursed by NYS Medicaid. Nathan Graber responded that there is not a separate reimbursement mechanism for screening with an AI-enabled device. There is a reimbursement methodology for tele-ophthalmology interpretation. Sanjiv Shah pointed out that Medicare does have a payment mechanism for AI-enabled screening devices for diabetic retinopathy. Elisabeth Benjamin noted that this technology could be particularly helpful for rural clinics. Nathan Graber supported this point and added that the Rural Health Transformation Program has a focus on AI and technology. Elisabeth Benjamin said that this kind of AI intervention is zero harm to the patient. Nathan Graber shared that the department has drafted recommendations for and against that the Committee will help to wordsmith. Before that, he emphasized an earlier point that the evidence shows that these devices are successful at ruling out more-than-mild diabetic retinopathy and add the convenience of receiving results received while the patient is still on-site, which may encourage compliance and appropriate follow-up. Sanjiv Shah

	added that point-of-care A1C testing also improves compliance and follow-up. James De Meo added that his practice sees, sadly, a lot of amputations, and they've observed a correlation between microvascular disease in the eyes and microvascular disease in the lower extremities. Perhaps this technology has potential downstream effects of preventing amputations, ulcerations, and hospitalizations. Emily Leish asked how Medicare's reimbursement compares to current Medicaid reimbursement of remote reading of tele-ophthalmology images. Nathan Graber clarified that rate setting is part of future coverage policy development, but the rate would likely be a percentage of Medicare's rate. Looking at the numbers, it may be lower than the current rate for CPT 92229. Emily Leish asked for the Committee's response to the fact that the American Academy of Ophthalmology (AAO) doesn't recommend AI-enabled screening for diabetic retinopathy. Elizabeth Brown from the Center for Evidence-based Policy clarified that AAO guideline does not recommend against the device, it states that the technology is promising and needs additional evidence. Marie-Carmel Garcon asked if these devices would be available in the primary care setting only, or other settings as well, such as gynecology, endocrinology, and pediatrics. Nathan Graber responded they would be an outpatient setting because primary care physicians would need access to it. He noted that the department would like the Committee's opinion on this if the devices are recommended for coverage. Nathan Graber asked if there was a consensus to start with a recommendation for or against. Thomas Smith motioned for a recommendation. Four committee members seconded the motion for a positive recommendation. Nathan Graber noted that 2 EBBRAC members had to leave early: Ronald Braithwaite and Deidre Wheat. He reiterated what Elisabeth Benjamin said off-mic: the committee does not do proxy votes, but Ronald Braithwaite did leave a message with her that if anybody asks, he is in favor of coverage. The initial draft recommendation was shared: *The Evidence-Based Benefit Review Advisory Committee recommends that the Department of Health establish a reimbursement mechanism for the use of AI-*

	enabled devices in outpatient clinical settings to screen for more-than-mild diabetic retinopathy in Medicaid members with the diagnosis of diabetes mellitus type 1 or type 2 who have not received an annual evaluation by an ophthalmologist and do not already have a diagnosis of diabetes-associated eye condition. Kate Breslin said the recommendation should be changed to say "ophthalmological evaluation." Nathan Graber suggested editing for the "ophthalmological exam." Warren Seigel suggested editing "to screen for diabetic retinopathy" instead of "more than mild diabetic retinopathy." All committee members agreed with this edit. Elisabeth Benjamin asked why the last sentence is needed: "who do not already have a diagnosis of diabetes-associated eye condition." Sanjiv Shah responded that FDA clearance is for people with diabetes who do not have diabetic retinopathy since it is a screening tool. Nathan Graber asked how to address any patients with glaucoma or cataracts, already seeing an ophthalmologist and probably getting screened for diabetic retinopathy. He asked how to edit the recommendation to be broader and specify this device should not be used for anyone with an existing eye condition under the care of an ophthalmologist. James De Meo suggested adding "and are not actively under the care…" to the draft recommendation. Sanjiv Shah recommended adding "and do not have a diagnosis of diabetic retinopathy." Nathan Graber noted that this level of detail would require department policy review, but the device should not be used for patients that already have an eye disease diagnosis. Nathan Graber shared his concern that the device could be used inappropriately, for example, for a patient with macular degeneration, glaucoma, or cataracts. He asked the committee how to address that concern in the recommendation. Elizabeth Brown from the Center for Evidence-based Policy shared that the FDA indication for 3 devices is for "adults diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy". Thomas Smith suggested mirroring the recommendation language with FDA language. Warren Seigel noted that the draft recommendation does not limit use to primary care settings. Nathan Graber responded that the devices should also be available in specialty clinics, particularly gynecologists, because there are requirements for screening for gestational

	diabetes. They may also be used in endocrinology, obesity, or other subspecialities. Kate Breslin asked about incorporating any age limitations. Nathan Graber suggested adding "18 years and above". Emily Leish asked if the Committee needs to define "AI-enabled devices" and Nathan Graber said that it is not necessary and that FDA approval is required based on state regulations and reimbursement policies. Jacob Wallace commented that there was very little evidence on algorithmic fairness in the review of these algorithms and if these devices become a substitute for human exams, it would be important for the Department of Health to try and understand algorithms used in the devices when deciding which product to adopt in Medicaid. Nathan Graber agreed. Jacob Wallace noted this information may be in the appendices of the studies. Elizabeth Brown from the Center for Evidence-based Policy noted that some studies did report results stratified by race but there were concerns on how authors defined race so instead of making decisions based on uninterpretable results, those findings were removed from body of the report (see appendices of report). Elizabeth Brown added that none of the devices provided information on which populations were used for training (e.g., Medicaid). Emily Leish asked if the department has heard from providers wanting to use this technology. Nathan Graber responded that if Medicaid enables coverage, providers get to make the decision on whether or not to use it. If Medicaid does not cover the devices, providers can still use the technology, they are just less incentivized to do so. Sanjiv Shah noted that 1 prominent FQHC in New York City already uses this technology. Marie-Carmel Garcon asked how often a patient could receive this exam, annually or bi-annually? Nathan Graber said that will be considered during policy drafting. A potential policy would be 1 billable exam per year per member. Nathan Graber asked if there was a motion to accept the amended recommendation. Elisabeth Benajmin made the motion, and Joe De Meo seconded it.

Action Items /Decisions	The Committee voted to approve the motion and accept the recommendation (14 yeas, 0 nay, 1 abstention; 2 departed prior to voting) Final, accepted recommendation: *The Evidence based Benefit Review Advisory Committee (EBBRAC) recommends that the Department of Health establish a reimbursement mechanism for the use of AI-Enabled Devices in outpatient clinical settings to screen for more than mild Diabetic Retinopathy in Medicaid members with the diagnosis of Diabetes Mellitus who have not received an annual evaluation by an ophthalmologist and do not already have a diagnosis of a diabetes-associated eye condition.*
Final Comments:	
Discussion	Nathan Graber thanked the Committee members for their time and discussion. He announced that the next EBBRAC meeting will be November 12, 2026, in New York City and will address: • Heartflow Fractional Flow Reserve from Computed Tomography (FFR-CT) Analysis for Noninvasive Identification of Coronary Artery Disease
Action Items /Decisions	Nathan Graber adjourned the meeting.