For Immediate Release

New CPT code for Automated Point-of-care Retinal Imaging

The AMA's CPT Editorial Panel has accepted a new category 1 CPT code for automated point-of-care retinal imaging, facilitating reimbursement of the IDx-DR exam

(Coralville, Iowa) June 25, 2019 – IDx, a privately held artificial intelligence (AI) diagnostics company, announced today that the American Medical Association's (AMA) Current Procedural Terminology (CPT) Editorial Panel has accepted a new category 1 CPT® code for automated point-of-care retinal imaging. This new code, submitted by the American Academy of Ophthalmology (AAO) with the support of IDx, facilitates correct billing of IDx-DR, an FDA-cleared autonomous AI system that detects diabetic retinopathy, a leading cause of blindness.

"This represents a significant milestone for autonomous AI in health care," said Michael Abramoff, MD, PhD, founder and CEO of IDx. "By accepting this new CPT code, the AMA's CPT Editorial panel has established a billing code for an AI-enabled system, which can help foster further adoption of autonomous AI technologies in healthcare. This will make billing the IDx-DR exam more straightforward for our customers, who have been billing for this sight-saving exam."

The AMA's CPT Editorial panel grants CPT codes, which are developed and reviewed by clinician experts as part of a transparent and open process, to provide a uniform language for submitting healthcare procedures and services for payor reimbursement. The new CPT code for automated point-of-care retinal imaging, scheduled to be effective in January 2021, will streamline the coding and billing process for healthcare providers using IDx-DR. The code description may be further refined prior to its scheduled implementation.

The AMA also issued a press release earlier this month further outlining policy recommendations for AI in healthcare. That policy includes advocating for "payment and coverage of all health care AI systems that are conditioned on complying with all appropriate federal and state laws and regulations, including but not limited to those governing patient safety, efficacy, equity, truthful claims, privacy, and security as well as state medical practice and licensure laws," among other criteria.

"It is exciting to see that our work aligns with the AMA's policy recommendations," said Abramoff. "When we developed and validated IDx-DR, it was our priority to show that the system was safe, effective, and equitable for use in patient care. We are thankful the AMA sees the value of supporting payment and coverage for AI health systems that meet rigorous validation. It is also incredibly important that AMA recommends autonomous AI developers assume accountability and liability for the system output, which we have been advocating for and practicing for years."

IDx-DR received a historic FDA clearance in 2018 when it became the first autonomous AI diagnostic system to be cleared for use without needing a physician to interpret the results. This enables non-eye care providers to use IDx-DR to make an immediate diagnostic assessment for diabetic retinopathy at the point of care, without requiring telemedicine or specialist review.

More than 30 million Americans have diabetes, and an estimated 24,000 lose vision each year from diabetic retinopathy, a complication of diabetes. If caught in its early stages, vision loss and blindness are almost entirely preventable, yet only about half of people with diabetes get regular eye exams. By enabling frontline healthcare providers to administer a diabetic retinopathy exam during a routine office visit, IDx-DR increases patient access to this potentially sight-saving exam.

IDx-DR has been used to test thousands of people with diabetes across the U.S. and Europe to date and is currently in use across a wide range of frontline care settings, including endocrinology, internal medicine, and community health clinics.

About IDx
IDx is a leading AI diagnostics company on a mission to transform the quality, accessibility, and affordability of healthcare. Founded in 2010 by a team of world-renowned clinician scientists, the company is focused on developing clinically-aligned autonomous AI that detect disease in medical images. By enabling diagnostic assessment in primary care settings, IDx aims to increase patient access to high-quality, affordable disease detection.

The company's first product, IDx-DR, is an FDA-cleared AI-based diagnostic system designed for use at the front lines of care to detect diabetic retinopathy. IDx-DR is intended for use by health care providers to automatically detect more than mild diabetic retinopathy in adults (22 years of age or older) diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy. IDx-DR is indicated for use with the Topcon NW400, an easy to use and highly accurate robotic fundus camera.

IDx is developing additional AI-based diagnostic systems for the detection of macular degeneration, glaucoma, Alzheimer's disease, cardiovascular disease, and stroke risk.

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