Press Release | August 4, 2020

Historic Proposed CMS Rule Will Allow First-Ever Reimbursement of Autonomous AI in a Healthcare Setting

Rule, coupled with HEDIS* update, will expand access to IDx-DR and increase point-of-care diagnoses of diabetic retinopathy and macular edema.

(Coralville, Iowa) August 4, 2020 – Blindness due to diabetic retinopathy and macular edema is largely preventable with early diagnosis. Today marked a major milestone for population health and the ability to expand specialty diagnoses into the primary care setting. The Centers for Medicare and Medicaid Services (CMS) made public their proposed rule for coverage of CPT® code 9225X (see page 271 of the linked PDF). It allows, for the first time, the safe, efficient, and equitable use of autonomous AI in a reimbursable primary care setting. The rule is a monumental step forward for autonomous AI and its ability to close care gaps in the healthcare system, especially when coupled with a recent update from the National Committee for Quality Assurance (NCQA) for the Comprehensive Diabetes Care HEDIS (Health Effectiveness Data and Information Set) measure language.

Digital Diagnostics' (formerly IDx) flagship product, IDx-DR, is an autonomous AI system that is FDA De Novo authorized; it provides instantaneous, point-of-care diagnostic assessment for diabetic retinopathy and macular edema using a process in which the computer makes the medical decision.

Under the new proposed coverage rule, healthcare providers can be reimbursed for their use of IDx-DR by Medicare payment under the Outpatient Prospective Payment System. Medicare coverage is crucial for delivering early diagnosis to the millions of patients with diabetes who do not have access to rapid or affordable specialist care.

"The potential for autonomous AI to improve access, heighten quality, and lower cost for patients is tremendous. Today's announcement is historic because it marks the first time CMS, the largest U.S. health payer, will cover the use of autonomous AI in healthcare," said Michael Abramoff, MD, PhD, founder and executive chairman of Digital Diagnostics (formerly IDx). "CMS coverage will make billing the IDx-DR exam even more straightforward for physicians, other healthcare providers, and healthcare organizations as well as their patients, thereby improving visual outcomes for at-risk populations."

The CMS proposed rule is complemented by the release in July 2020 of an update to NCQA's HEDIS comprehensive diabetes care measure. The HEDIS update allows autonomous AI to be used to close the diabetic eye exam care gap, meet the measure, and thereby unlock financial incentives for healthcare systems to expand access to early diagnosis.

Early Diagnosis: Preventing Blindness in At-Risk Populations

Expanding coverage and use of AI expands healthcare access in underserved communities and lowers the cost of care for all. Further, it allows specialists to practice "top of license," focusing their valuable time on those patients who need specialist care the most.

Preventing blindness is at the heart of both the IDx-DR system and the CMS proposed ruling; earlier diagnosis of more cases means more patients with diabetic retinopathy can keep their vision. More than 30 million Americans have diabetes, and an estimated 60,000 lose vision each year from diabetic retinopathy, a number that is heavily skewed toward people of color. If caught in its early stages, vision loss and blindness are almost entirely preventable, yet less than half of people with diabetes get regular eye exams. By enabling frontline healthcare providers to administer a diabetic retinopathy exam, the IDx-DR offers diagnosis during a standard diabetes management visit.

How does Digital Diagnostics' IDx-DR work?

Envisioned by Michael Abramoff, MD, PhD, a practicing, fellowship-trained retina specialist ophthalmologist, neuroscientist and computer engineer, IDx-DR is the first autonomous AI system ever to receive FDA De Novo authorization. The system diagnoses diabetic retinopathy and diabetic macular edema in front-line healthcare settings. Because a visit to a specialist requires another trip to another doctor, another co-pay, and for some patients, a long wait for an appointment, autonomous AI technology, which does not require a specialist operator, expands access to earlier disease diagnosis and ultimately improves outcomes. While IDx-DR is already in use, when the CMS code goes into effect on January 1, 2021, the coverage from the Medicare Outpatient Prospective Payment System will enable primary care physicians and other healthcare providers to be reimbursed for the use of IDx-DR.

IDx-DR Regulatory Timeline

IDx has worked in concert with patient and physician organizations as well as Federal agencies at every step of its journey toward expanding access to early diagnosis:

- **Feb. 2018:** IDx-DR receives "Breakthrough Device" designation from the FDA
- **Apr. 2018:** First time FDA issues de novo authorization for an autonomous AI, IDx-DR, in any field of medicine, to be safe, efficient, and equitable.
- **June 2018:** Introduction of a temporary bridge coding I CPT® code 92250-TC for autonomous AI for diagnosing diabetic retinopathy and diabetic macular edema
- **May 2019:** AMA's CPT® Editorial Panel creates for the first time a CPT® category I code 9225X for autonomous AI, which makes a clinical decision without specialist review, to go into effect Jan 1 2021
- **Dec. 2019:** American Diabetes Association updates its Standard of Diabetes Care to include autonomous AI for diabetic retinopathy.
- **July 6, 2020:** NCQA announces an update to HEDIS so it supports the use of autonomous AI for the diabetic eye exam. The HEDIS updates announced on July 6, 2020 are summarized here.
- **August 3, 2020:** CMS announces coverage of CPT® code 9225X.

The CMS rule and the new Category I CPT® code are effective January 1, 2021. The expansion of coverage to patients who are eligible for Medicare is a critical step in increasing affordability, accessibility and equity in healthcare.

About Digital Diagnostics (DxS)

DxS (dxs.ai), formerly IDx, is a pioneering AI diagnostics company on a mission to transform the quality, accessibility and affordability of healthcare. Founded and led by Michael Abramoff, MD, PhD, a fellowship-trained retina specialist ophthalmologist, neuroscientist and computer engineer, DxS developed a patented biomarker-based approach to build autonomous algorithms that make clinical decisions without human intervention. DxS and its flagship product IDx-DR, an autonomous AI system with FDA De Novo authorization to diagnose diabetic retinopathy and diabetic macular edema, has proven that intelligent diagnostic platforms can be used safely, efficiently and equitably to improve patient outcomes. As it expands into other diagnostic capabilities, DxS has paved the way for automated diagnosis to become a new standard of care that will contribute significantly to democratizing healthcare. Learn more at www.dxs.ai.

*About NCQA HEDIS Measures

The Healthcare Effectiveness Data and Information Set (HEDIS) is one of health care's most widely used performance improvement tools; it is a system administered by the National Committee for Quality Assurance (NCQA). Approximately 191 million people are enrolled in plans that report HEDIS results. For more information, visit https://www.ncqa.org/hedis/. The measures announced on July 6, 2020 are summarized here.

About CMS

The Centers for Medicare & Medicaid Services (CMS) is a federal agency in the US Department of Health and Human Services (HHS) that administers the Medicare program and works in partnership with state governments to administer Medicaid, the Children's Health Insurance Program (CHIP), and health insurance portability standards. For more information, visit https://www.cms.gov/newsroom/press-kit.

For more information:

https://www.dxs.ai

For media interviews:

Patricia Agos, patricia@akrete.com, 773-758-5044

General Contact

Digital Diagnostics, LLC

info@dxs.ai
319 248 5620

2300 Oakdale Blvd.
Coralville, IA 52241

www.dxs.ai

Direct Contact

Olivia Niederhauser

Communications Specialist

319 981 0037

niederhauser@dxs.ai

Media Contact

Patricia Agos

Akrete Communications

773 758 5044

patricia@akrete.com