What Are Reimbursement Policies for AI Diagnostics? Navigating the Digital Health Payment Landscape

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Abstract

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The integration of Artificial Intelligence (AI) into diagnostic medicine represents a paradigm shift, promising enhanced accuracy, efficiency, and access to care. However, the path from regulatory approval to widespread clinical adoption is often bottlenecked by a complex and evolving challenge: **reimbursement policies**. For AI diagnostics to realize their full potential, sustainable and predictable payment models must be established. This analysis explores the current state of AI diagnostics reimbursement, the primary challenges, and the legislative efforts underway to modernize the payment landscape for digital health technologies.

The Current State of AI Diagnostics Reimbursement

Reimbursement for AI-enabled medical devices and software falls into two primary categories: **assistive AI** and **autonomous AI**. Assistive AI aids a clinician in making a diagnosis, while autonomous AI makes a clinical decision without human oversight. The payment mechanisms for these technologies are currently a patchwork of existing codes and new, technology-specific pathways, primarily within the United States Medicare system.

A landmark moment for autonomous AI came with the U.S. Centers for Medicare and Medicaid Services (CMS) establishing a national payment amount for the first FDA *de novo* authorized autonomous AI system, IDx-DR (Digital Diagnostics) [1]. This system, which diagnoses diabetic retinopathy, was granted payment under both the Medicare Physician Fee Schedule (MPFS) and the Outpatient Prospective Payment System (OPPS). This payment is facilitated by the dedicated Current Procedural Terminology (CPT)

code **92229**, which specifically covers "Imaging of retina for detection of eye disease (e.g., diabetic retinopathy) with automated point-of-care analysis" [2]. The creation and use of this code signal a critical step toward recognizing the independent value of autonomous AI diagnostics.

For other innovative AI technologies, the primary avenue for temporary payment has been the **New Technology Add-on Payments (NTAP)** program under the Inpatient Prospective Payment System (IPPS). NTAP provides additional payments for new medical services or technologies that demonstrate substantial clinical improvement [3]. While successful for some assistive AI systems, such as those for stroke detection (Viz.LVO) and cardiac ultrasound guidance (Caption Health), the NTAP pathway is inherently limited.

The Challenge of Outdated Payment Models

Despite these initial successes, the current reimbursement framework presents significant hurdles that slow the adoption of beneficial AI diagnostics.

1. Limitations of NTAP

The NTAP program, while helpful, is not a sustainable long-term solution for AI. Its limitations include: ***Inpatient Focus:*** *NTAP is restricted to services provided in the inpatient setting, failing to cover the vast majority of AI diagnostics used in outpatient or physician office settings.* **Time-Limited:** Payments are temporary, lasting only three years, after which the technology must be integrated into existing bundled payments, often leading to a reduction or elimination of specific payment. ***High Bar for Entry:*** *The requirement for "newness," cost, and "substantial clinical improvement" makes the approval process complex and difficult for many AI innovations to satisfy [1].*

2. Inconsistent Coverage for SaMD

Many AI diagnostics are classified as ***Software as a Medical Device (SaMD)****. Reimbursement for SaMD remains inconsistent across public and private payors, failing to keep pace with the rapid growth and potential of AI-enabled devices [4]. The lack of a clear, standardized pathway for valuing and paying for software-only solutions creates financial uncertainty for developers and limits patient access.*

Legislative Efforts to Modernize Reimbursement

Recognizing the need for a dedicated and predictable payment mechanism, policymakers have introduced legislation aimed at creating a clear path for AI diagnostics. The ***Health Tech Investment Act (S. 1399)****, introduced by Senators Mike Rounds and Martin Heinrich in 2025, proposes to amend Title XVIII of the Social Security Act to establish a consistent Medicare payment pathway for algorithm-based healthcare services (AHBS) [5].*

This proposed legislation seeks to: **Create a Predictable Pathway:** Move beyond the temporary nature of NTAP and establish a long-term, predictable

payment system. ***Accelerate Patient Access:*** *Ensure that Medicare beneficiaries can access FDA-approved AI technologies sooner.* **Incentivize Innovation:** Provide financial certainty to innovators, encouraging further development of high-value AI diagnostics.

The successful passage of such legislation would represent a monumental shift, providing the necessary financial infrastructure to support the widespread adoption of AI in medicine.

The Path Forward for Digital Health

The future of AI diagnostics hinges on the successful navigation of these reimbursement challenges. The shift from paying for volume to paying for value is crucial, and AI is uniquely positioned to demonstrate value through improved outcomes and reduced costs. The ongoing dialogue between regulators, payors, clinicians, and AI developers is essential to crafting a framework that is ethically sound, transparent, and financially sustainable. The current landscape, characterized by the landmark CPT code 92229 and the promise of the Health Tech Investment Act, shows a clear trajectory toward a more rational and supportive environment for AI innovation. However, the true measure of success will be the speed and equity with which these policies translate into improved patient outcomes and broader access to cutting-edge diagnostic tools. The next few years will be critical in determining whether the financial infrastructure can keep pace with the rapid technological advancements in AI diagnostics.

For more in-depth analysis on the intersection of digital health, AI, and healthcare economics, the resources at [www.rasitdinc.com] (https://www.rasitdinc.com) provide expert commentary and professional insight.

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