

## ORIGINAL ARTICLE

# Characterizing the Clinical Adoption of Medical AI Devices through U.S. Insurance Claims

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## Abstract

There are now over 500 medical artificial intelligence (AI) devices that are approved by the U.S. Food and Drug Administration. However, little is known about where and how often these devices are actually used after regulatory approval. In this article, we systematically quantify the adoption and usage of medical AI devices in the United States by tracking Current Procedural Terminology (CPT) codes explicitly created for medical AI. CPT codes are widely used for documenting billing and payment for medical procedures, providing a measure of device utilization across different clinical settings. We examined a comprehensive nationwide claims database of 11 billion CPT claims between January 1, 2018, and June 1, 2023 to analyze the prevalence of medical AI devices based on submitted claims. Our results indicate that medical AI device adoption is still nascent, with most usage driven by a handful of leading devices. For example, only AI devices used for assessing coronary artery disease and for diagnosing diabetic retinopathy have accumulated more than 10,000 CPT claims. Furthermore, we found that zip codes that had a higher income level, were metropolitan, and had academic medical centers were much more likely to have medical AI usage. Our study sheds light on the current landscape of medical AI device adoption and usage in the United States, underscoring the need to further investigate barriers and incentives to promote equitable access and broader integration of AI technologies in health care.

## Introduction

**A**s artificial intelligence (AI) has rapidly progressed in recent years, significant investments have been devoted to developing and commercializing AI in medicine. As of 2023, over 500 medical AI devices have undergone U.S. Food and Drug Administration (FDA) evaluation and received approval across areas such as radiology, neurology, and pathology.<sup>1</sup> During an FDA submission, device manufacturers are required to report evidence of the efficacy and safety of their products, providing crucial

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insight into how AI algorithms are evaluated before being used on patients.<sup>2</sup> However, after approval, companies rarely share where and when their products are used. As such, despite the proliferation of medical AI approvals, little is known about their real-world usage.

The usage and adoption patterns of medical AI devices can significantly affect their clinical impact. First, the performances of AI algorithms are notoriously susceptible to changes in health care settings and fluctuate during deployment.<sup>3,4</sup> For instance, despite initial studies indicating up to a 20% improvement in detection rates, computer-aided detection (CAD) products for mammography approved in the early 2000s have been found to provide no tangible benefits to women.<sup>5</sup> This discrepancy has been attributed to adoption and usage factors such as changes in clinician interaction with the software and the transition from film to digital mammograms.<sup>6</sup> Consequently, although AI medical devices may demonstrate strong performance under specific evaluation conditions, variations in real-world applications can yield drastically different outcomes. Second, the impact of medical AI devices is mediated by economic forces. After FDA approval, companies need to find sustainable revenue streams for the promises of AI-driven health care to be realized. Different reimbursement approaches can affect how often and on whom these devices are used, and it is still unclear which model is optimal for the new AI devices.<sup>7,8</sup> Studying the empirical usage of medical AI devices is a crucial step in characterizing the landscape of medical innovations and can provide a more holistic view of the translational pipeline from algorithm to patient.

Recently, Current Procedural Terminology (CPT) codes have been created specifically for medical AI devices.<sup>7,8</sup> CPT codes are designated by the U.S. Department of Health and Human Services under the Health Insurance Portability and Accountability Act as a national coding set for physicians and other health care professional services and procedures to be used by the Centers for Medicare & Medicaid Services (CMS).<sup>9</sup> The codes are regularly created, updated, and modified by the American Medical Association (AMA) and are the most widely accepted medical nomenclature under public and private health insurance programs.<sup>9</sup> Health care providers use these codes to generate itemized bills detailing the specific services delivered to a patient during a medical encounter. Subsequently, these bills are submitted to insurance companies, who use the coded information to determine the appropriate reimbursement for the services rendered. As such,

CPT codes play a crucial role in ensuring the accuracy and uniformity of medical billing, as well as promoting accountability and transparency within the health care system.

CMS also provides coverage for medical AI devices through a new technology add-on payment (NTAP), which is specifically designed to encourage health care providers to adopt new technologies.<sup>7</sup> However, the NTAP program specifically focuses on inpatient payments, whereas CPT codes apply to both inpatient and outpatient settings.<sup>10,11</sup> In this article, we focus on CPT codes because they are most widely adopted and standardized across both public and private insurance programs,<sup>9</sup> whereas the NTAP approach is specifically used within Medicare,<sup>11</sup> presenting only a partial view of national AI usage. Additionally, because of its extensive and long-term adoption by health care payers, CPT is also an informative resource for comparing baseline usage rates of non-AI devices.

Although an increasing number of CPT codes have been made available for medical AI devices, these codes are generally spread across various medical domains and reserved for medical coders and insurance companies. As such, there currently does not exist a single database of AI-related CPT codes or a systematic analysis of their usage. In this article, we identify and organize a comprehensive list of CPT codes that apply to medical AI devices. We analyze the usage of these codes on a large national claims database and present their temporal and geographic trends.

## RELATED WORKS

Previous analyses have focused on translational roadblocks for medical AI devices stemming from model evaluation, ethics, and reporting.<sup>2,12</sup> Specific studies have shown how AI algorithms can perform worse in clinical practice despite promising retrospective evaluations.<sup>13,14</sup> A variety of studies have analyzed the emergence of reimbursement mechanisms for medical AI products. For example, researchers have highlighted Viz.ai's NTAP model and its potential impact on stroke care, as well as the economic challenges of adopting LumineticsCore from a cost-benefit perspective.<sup>11,15</sup> Current payment models for AI have been previously analyzed along with examples of reimbursable AI devices.<sup>7</sup> More specifically, a recent study has proposed a framework for analytically determining the value and cost of each unique AI service in order to encourage ethical and optimal deployment.<sup>8</sup>

Although our work is the first to analyze AI usage through CPT codes, several studies have analyzed geographic distributions present in AI development. For example, researchers have analyzed PubMed for the training datasets used in various medical AI algorithms and found that the data are disproportionately located in California, Massachusetts, and New York.<sup>16</sup> Datasets used in AI skin cancer diagnosis have also been exclusively found to be from Europe, North America, and Oceania.<sup>17</sup> The usage of CPT codes for digital health technologies like remote physiologic monitoring, e-consults, and e-visits have also been systematically studied by reporting the total number of claims in Medicare data.<sup>18</sup> Our work focuses specifically on the subset of digital health relevant to AI and machine learning (ML).

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## Methods

Our analysis consists of two main parts: the organization of medical AI device CPT codes and the analysis of their usage. First, to find CPT codes used for medical AI devices, we used a combination of official sources, Web resources, and insurance company policies. Second, we searched a large national claims database to quantify the usage of each code.

### COLLECTING CPT CODES FOR MEDICAL AI DEVICES

#### *Official AMA Sources*

The AMA develops CPT codes and is responsible for the development of new billing codes for medical AI products. The CPT Editorial Panel has issued guidance for classifying AI applications, which includes assistive, augmentative, and autonomous work,<sup>19</sup> but only a few examples of AI codes are referenced. For a comprehensive list of new CPT codes, we processed the AMA's list of Category III codes (accessed March 1, 2023<sup>20</sup>), which are a set of temporary codes assigned to emerging technologies, services, and procedures.<sup>21</sup> Although these codes are billed like all other codes, Category III codes are intended to be used primarily for data collection to substantiate widespread usage before granting reimbursement. After 5 years, they are reevaluated and replaced with a Category I code if deemed qualified. We analyzed each of the AMA's Category III codes (long descriptors) for the terms *artificial intelligence* and *machine learning* and their variants. Next, for Category I and II codes, we performed a

comprehensive search using Codify by AAPC, a search engine for CPT codes.<sup>22</sup>

CPT code long descriptors provide limited information on the underlying technology behind the procedure and the product name. Therefore, we complemented the CPT code descriptions with details provided by insurance companies in policy documents. Such documents provide detailed descriptions of a given procedure, as well as any medical evidence that might support the case for its reimbursement. Additionally, the policies often reference specific product names that the CPT codes refer to. We analyzed the policies of Premera, Amerigroup, and Blue Cross and noted products that were referred to as AI or ML devices.<sup>23-25</sup>

#### *Determining AI Devices*

We determined whether each candidate CPT code bills for an AI medical device if either of the following criteria was met: the device manufacturer makes explicit marketing claims that its product uses AI and/or ML, or a third party (e.g., insurance company or news publication) refers to the product as powered by AI and/or ML. Additionally, we excluded CPT codes that are also used for billing non-AI devices, because this dilutes the number of AI-specific occurrences. For example, recently, AI has been integrated into a continuous glucose monitoring device, but other non-AI devices are billed under the same code. Another example includes mammography with CAD, which is largely dominated by traditional CAD and should be differentiated from modern CAD products.<sup>26</sup> As a whole, radiology AI devices are underrepresented in our analysis relative to their share of all FDA-approved AI devices<sup>27</sup> because they are commonly billed using existing CPT codes that are not specific to AI. However, more procedures in areas like cardiology (e.g., HeartFlow's FFRCT analysis) do not have non-AI counterparts, allowing for the creation of new CPT codes that are AI specific. Next, several CPT codes exist for ML-based proprietary laboratory tests (identified with the letter "U"), but are excluded from this study because they are typically designed and deployed in specific laboratories and are outside the FDA's purview.<sup>28</sup> Finally, to focus our analysis on the usage of recently developed AI, we include only CPT codes developed after 2015.

#### *Grouping CPT Codes*

Multiple CPT codes may be related to the same underlying medical procedure but describe different aspects of

the procedure. For example, both 0648T and 0649T are used to report quantitative magnetic resonance (MR) analysis of tissue composition, but 0649T is used when diagnostic magnetic resonance imaging (MRI) is also completed, whereas 0648T is used when it is not. In our analysis, we organized codes that refer to the same underlying medical AI procedure into a CPT code group. To this end, we computed the sum total of all codes in that code group when reporting the number of claims for each procedure.

## CLAIMS DATA

### *IQVIA PharMetrics® Plus*

We used the IQVIA PharMetrics® Plus for MedTech dataset, a longitudinal health plan database of medical and pharmacy claims.<sup>29</sup> The dataset consists of more than 210 million unique U.S. enrollees and comprises largely commercial health plans. The data are compliant with the Health Insurance Portability and Accountability Act and are representative of the commercially insured U.S. national population for patients under 65 years of age.<sup>30</sup> The IQVIA dataset is commonly used for analyses of medical trends in areas like infectious diseases,<sup>31-35</sup> cardiology,<sup>36</sup> dermatology,<sup>37</sup> pulmonology,<sup>38</sup> oncology,<sup>39</sup> and neurology.<sup>40-42</sup> The unit measurement we used in our analysis is a medical claim that uses a CPT code associated with a medical AI procedure. We analyzed usage in all 50 U.S. states from January 1, 2015, to June 1, 2023; the dataset consists of 16 billion claims in total, with 11 billion claims after 2018. We have included a table that details the number of claims in our dataset for each year between 2015 and 2023 (Table S3). As a point of reference, CMS reports that there are a total of 5 billion claims processed in the United States per year,<sup>43</sup> which suggests that our dataset has approximately 40% coverage of all U.S. claims.

### *Finding Associated Device Names and FDA Approvals*

To provide the commercial context for each CPT code, we also located specific device names associated with each AI CPT code by searching through insurance policies as well as company websites. Although we were able to locate at least one product for each procedure, the list may not be comprehensive if a product was not indicated by the company or a third-party source. For the top products we found, we also located their corresponding FDA approval (if applicable) to provide a timeline context for the overall translational pipeline for each product.

## *Geographic Analysis*

For each medical AI procedure, we aggregated all unique zip codes that contained an occurrence of at least one code. First, we searched for each zip code's median income and classified it as high income if it exceeded \$100,000 per year, consistent with the IRS's classification.<sup>44</sup> Next, we determined whether it was in a metropolitan area by referencing the U.S. Department of Agriculture's Rural-Urban Commuting Area Codes.<sup>45</sup> Finally, we computed the percentage of all unique zip codes that had a high median income level and were metropolitan. We compared these rates with the rates found for all U.S. zip codes, as well as unique zip codes found in a random sample of 1 million claims (across all CPT codes).

## *Insurance Pricing*

In addition to CPT code billing frequencies, we collected public and private pricing information. First, when available, we looked up Medicare pricing for each CPT code that had been made publicly available each year.<sup>46</sup> Second, we gathered negotiated pricing rate data from Anthem Healthcare in California and New York, focusing specifically on in-network rates as of November 2022. These data are made available as part of the Transparency in Coverage regulation, which was introduced by the Tri-Agencies (U.S. Departments of Health and Human Services, Labor, and Treasury) on November 12, 2020.<sup>47</sup> The regulation requires health plans to publish their negotiated rates for all items and services for commercial coverage, including in-network files, in machine-readable formats, with monthly updates starting from July 1, 2022. We utilized the November 2022 version of the in-network rate files, which are provided in the CMS-defined JSON (Java Script Object Notation) format.

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## Results

### BILLABLE MEDICAL AI DEVICES

Given our methodology, we found a total of 16 medical AI procedures billable under CPT codes. Several procedures can be reimbursed through multiple codes, comprising a total of 32 unique CPT codes that are associated with AI. These procedures are detailed in [Table 1](#), alongside the total number of claims containing the codes, product name, and effective date of the codes. The procedures fall within a wide range of health care areas, such as cardiology, radiology, and ophthalmology, and were created very

Table 1. Summary of AI CPT Codes.*				
Total Claims	Condition or Medical AI Procedure	CPT Code(s)	Example Product Name	Effective Date
67,306	Coronary artery disease	0501T–0504T	HeartFlow Analysis <sup>48</sup>	June 1, 2018
15,097	Diabetic retinopathy	92229	LumineticsCore <sup>49</sup>	January 1, 2021
4,459	Coronary atherosclerosis	0623T–0626T	Cleerly <sup>50</sup>	January 1, 2021
2,428	Liver MR	0648T–0649T	Perspectum LiverMultiScan <sup>51</sup>	January 1, 2021
591	Multiorgan MRI	0697T–0698T	Perspectum CoverScan <sup>52</sup>	January 1, 2022
552	Breast ultrasound	0689T–0690T	Koios DS <sup>53</sup>	January 1, 2022
435	ECG cardiac dysfunction	0764T–0765T	Anumana <sup>50</sup>	January 1, 2023
331	Cardiac acoustic waveform recording	0716T	CADScor <sup>50</sup>	July 1, 2022
237	Quantitative MR cholangiopancreatography	0723T–0724T	Perspectum MRCP+ <sup>54</sup>	July 1, 2022
67	Epidural infusion	0777T	CompuFlo <sup>55</sup>	January 1, 2023
4	Quantitative CT tissue characterization	0721T–0722T	Optellum Virtual Nodule Clinic <sup>56</sup>	July 1, 2022
1	Autonomous insulin dosage	0740T–0741T	d-Nav <sup>57</sup>	January 1, 2023
1	CT vertebral fracture assessment	0691T	HealthVCF <sup>50</sup>	January 1, 2022
1	Noninvasive arterial plaque analysis	0710T–0713T	ElucidVivo <sup>50</sup>	January 1, 2022
0	Facial phenotype analysis	0731T	Face2Gene <sup>50</sup>	July 1, 2022
0	X-ray bone density	0749T	OsteoApp <sup>50</sup>	January 1, 2023

\* A total of 16 medical AI procedures are presented alongside their corresponding CPT codes. Each procedure is associated with an example commercial product that may be reimbursed through the codes. The effective date is the date on which the code was officially recognized by the American Medical Association and can be used for billing and reimbursement purposes. The total claims listed are recent as of June 1, 2023. AI denotes artificial intelligence; CPT, Current Procedural Terminology; CT, computed tomography; ECG, electrocardiogram; MR, magnetic resonance; MRCP, magnetic resonance cholangiopancreatography; and MRI, magnetic resonance imaging.

recently, with 15 of 16 medical AI procedures created since 2021 (Fig. 1). We found that only 4 of 16 have more than 1000 total claims. This is partially because the median age of a medical AI procedure is only about a year (374 days).

### GROWTH PATTERNS OF MEDICAL AI DEVICES

We found that the overall utilization of medical AI products is still limited and focused on a few leading procedures. However, utilization has generally increased exponentially for each medical AI procedure (Fig. 2). The procedure with the most AI usage is coronary artery disease (n=67,306; effective January 1, 2018). The associated CPT codes can be used to reimburse products like HeartFlow FFRCT, a medical device that uses computed tomography (CT) scans to create a 3D model of the coronary arteries. The model is then used to calculate the fractional flow reserve (FFR), which is a measure of how well blood flows through the arteries. Among other functions, FFRCT can be used to diagnose coronary artery disease and assess the severity of the disease.<sup>58</sup> HeartFlow FFRCT was given its first FDA approval in 2019 and has had two subsequent updates since.<sup>59</sup> In November 2021, CMS set the national payment rate of the device at \$930.34 for an office-based setting.<sup>60</sup> Meanwhile, privately negotiated rates from Anthem in California and New York have a median price of \$909.77.

Diabetic retinopathy medical AI has also grown exponentially in usage (n=15,097, effective January 1, 2021). The first FDA approval in this category was given on January 12, 2018, to LumineticsCore,<sup>61</sup> an AI diagnostic system that autonomously diagnoses patients for diabetic retinopathy (including macular edema).<sup>62</sup> It is indicated for use by health care providers to automatically detect more than mild diabetic retinopathy in adults diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy.<sup>61</sup> The product takes images of the back of the eye, analyzes them, and provides a diagnosis. If more than a mild case is detected, the patient is referred to a specialist.<sup>63</sup> In 2021, the national payment rate set by CMS for CPT code 92229 was \$45.36,<sup>49</sup> whereas the median privately negotiated rate was \$127.81.

We also found exponential growth at a smaller scale occurring in medical AI for coronary atherosclerosis and liver MR. Cleerly's Coronary Computer Tomography Angiography (CCTA) algorithm (n=4459, effective January 1, 2021) received its first FDA approval on October 9, 2019, and aims to identify atherosclerosis, the plaque buildup in the arteries of the heart, as well as vascular morphology features for all identified arteries in the CCTA data.<sup>64</sup> Although pricing for this code is not given through CMS, we found it has a median private negotiated



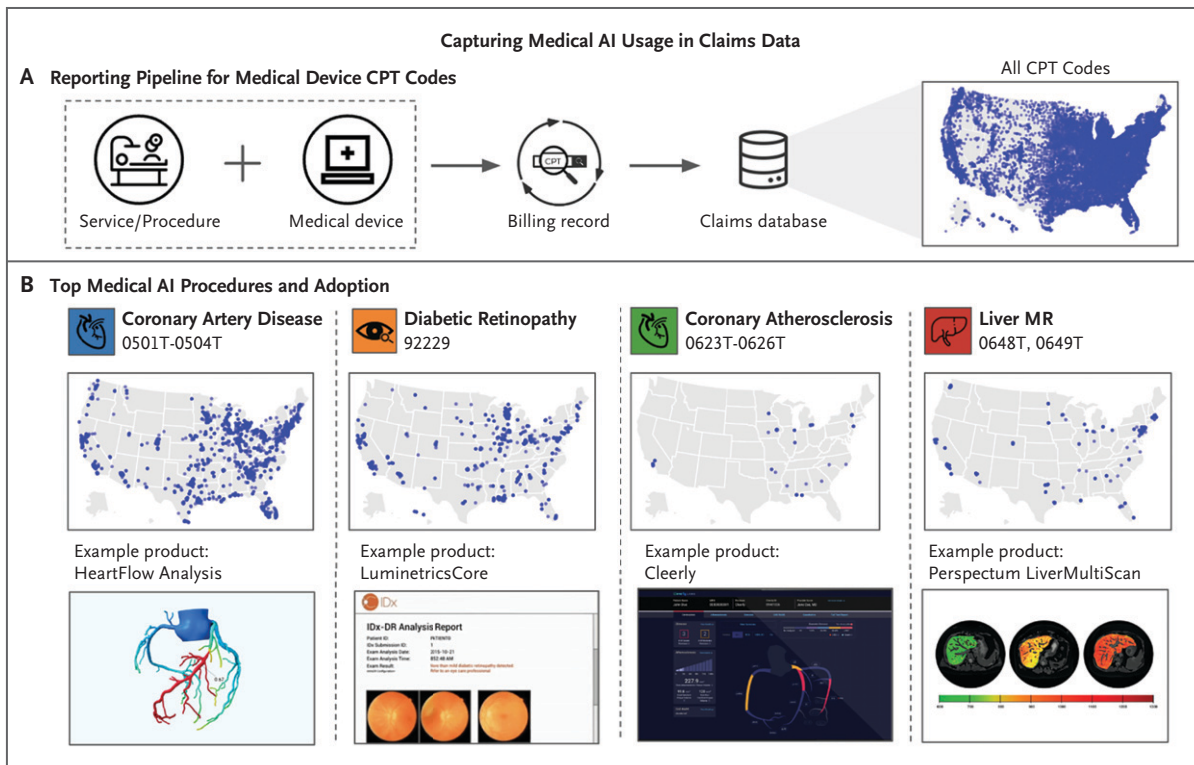


Figure 1. Capturing Medical AI Usage in Claims Data.

Panel A shows the reporting pipeline for CPT codes. Medical device usage is captured through billing records and aggregated in our claims database. Each service/procedure that uses a medical device is associated with a CPT code that hospitals and medical practices report for billing purposes. On the right, we provide a map of the geographic distribution of zip codes for a random sample of 1 million claims (out of 11 billion in our dataset from January 1, 2018, to June 1, 2023) for comparison with AI CPT codes. Each blue dot represents a single unique zip code where the procedure was billed. Panel B provides details on the top four billable medical AI procedures through CPT codes. Under the procedure name, we list the CPT codes and a map of the geographic distribution of zip codes where they have been billed (cumulative over time). In the bottom row, we provide examples of billable products under each code and a product description image taken from marketing materials from the respective companies. AI denotes artificial intelligence; CPT, Current Procedural Terminology; and MR, magnetic resonance.

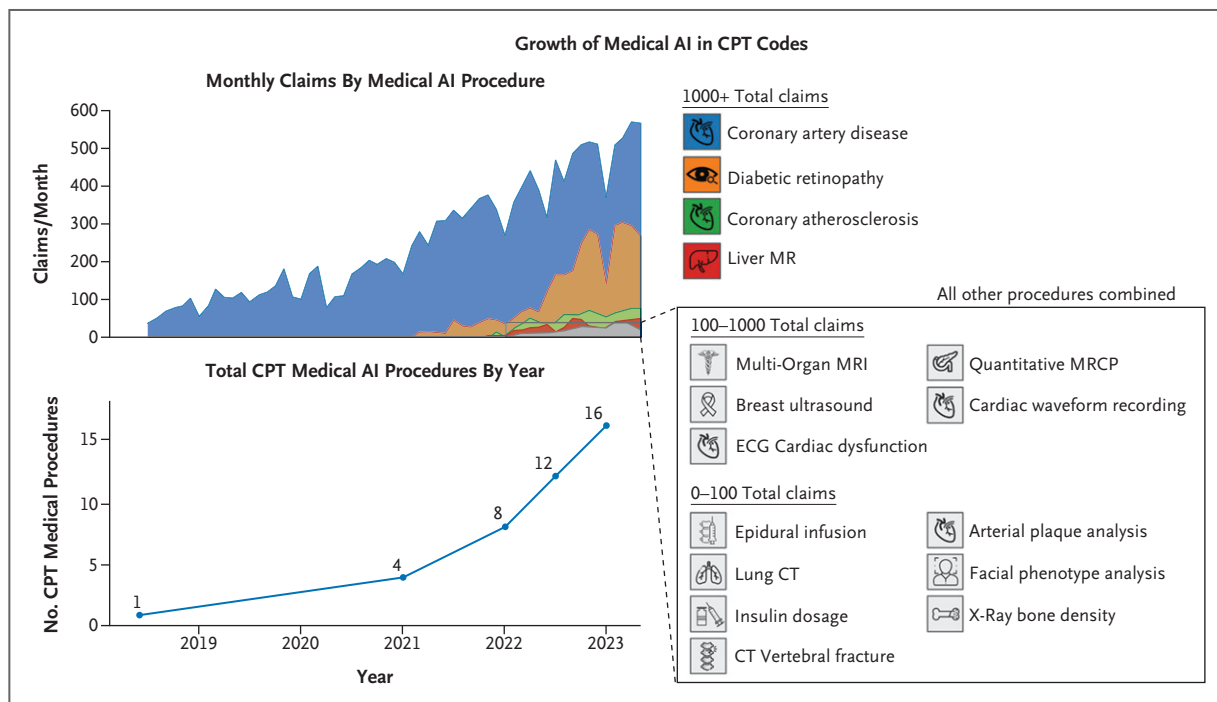
rate of \$692.91. Perspectum's LiverMultiScan (n=2428, effective January 1, 2021) is a noninvasive diagnostic technology for evaluating liver diseases present in multiparametric MRI by quantifying liver tissue.<sup>65</sup> Receiving its FDA approval on September 6, 2017, it provides a number of quantification tools, such as region-of-interest placements, to be used for the assessment of regions of an image to aid in the diagnosis of liver disorders.<sup>59</sup> The associated CPT code, 0648T, does not have a national payment rate through CMS but has a median privately negotiated rate of \$371.55. We include a full table of available pricing information in Table S2.

Finally, we also observed that several procedures had only nominal or zero usage. CT Vertebral Fracture Assessment and Noninvasive Arterial Plaque Analysis had only a single

occurrence in our CPT database since January 1, 2022, and procedures (Facial Phenotype Analysis and X-Ray Bone Density) did not have any occurrences in our database.

### CHARACTERISTICS OF DEPLOYED ZIP CODES

To better understand the drivers of medical AI device adoption, we represented each zip code by three features: whether it had a high median income level (median annual household income greater than \$100,000), whether it was metropolitan (classification by the U.S. Department of Agriculture), and whether it had at least one academic hospital (determined by the Association of American Medical Colleges). We performed logistic regression on the outcome variable of AI adoption within a



**Figure 2. Growth of Medical AI in CPT Codes.**

Panel A presents the number of claims per month for each medical AI procedure between January 1, 2018, and June 1, 2023. The top four procedures by total claims are presented in colors, whereas the remaining 12 are grouped and added together into an “Other” group in gray. On the right-hand side, we provide a legend for each of the medical AI procedures. These procedures are further grouped by their usage tiers (0 to 100, 100 to 1000, and  $\geq 1000$  total claims). All procedures in the “Other” category are contained in the callout box on the bottom right. Panel B presents the cumulative number of CPT AI medical procedures available each year from 2018 to 2023. AI denotes artificial intelligence; CPT, Current Procedural Terminology; CT, computed tomography; ECG, electrocardiogram; MR, magnetic resonance; MRCP, magnetic resonance cholangiopancreatography; and MRI, magnetic resonance imaging.

zip code (defined as at least one occurrence of billing of an AI CPT code) (Table 2). Only zip codes with at least one institutional NPI (National Provider Identifier) were included in our analysis. In total, we included 22,704 zip codes, of which 2182 had at least one medical AI billing. All three variables were statistically significant ( $P < 0.001$ ), whereas the presence of an academic hospital had the largest effect on the likelihood of AI adoption (17 times more likely). Metropolitan zip codes had the second

largest effect (5.25 times more likely), whereas high-income zip codes had a 1.45 times likelihood of AI adoption. Of all zip codes with an academic hospital, 71% had at least one medical AI billing. In contrast, only 9% of zip codes without an academic hospital had at least one medical AI billing. We also found a difference between high income and low income (18% vs. 9%) and metropolitan versus nonmetropolitan (14% vs. 3%) zip codes in whether the area had at least one medical AI billing.

**Table 2. A Multivariate Logistic Regression on Whether a Zip Code Has at Least One Documented Billing of a Medical AI CPT Code.\***

Zip Code Characteristic	Log-Odds Coefficient
High income	0.373 <sup>†</sup>
Metropolitan	1.65 <sup>†</sup>
Has academic hospital	2.85 <sup>†</sup>

\* Only zip codes with at least one institutional NPI (National Provider Identifier) are included in the analysis ( $n=22,704$ ). AI denotes artificial intelligence, and CPT, Current Procedural Terminology.

<sup>†</sup>  $P < 0.001$ .

Consistent with the results from our regression model, 32% of zip codes where AI devices are deployed are high income, which is significantly higher than non-AI claims (17%,  $P < 0.001$ ) as well as the U.S. general population average (10%,  $P < 0.001$ ). An average of 89% of the zip codes for AI are metropolitan, which is much higher than the U.S. average (41%,  $P < 0.001$ ) and marginally higher than the value for the random sample of non-AI claims (87%,  $P = 0.002$ ) (Fig. S2). Additionally, we created a map of the geographic distribution of claims for the top four

medical AI procedures for each year of their availability and found that usage is generally well distributed across coasts and regions of the United States (Fig. S1). We also list the top 10 zip codes and city/state for each of the top four medical AI procedures in our analysis (Table S1).

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## Discussion

Our study found that the commercialization of FDA-approved AI products is still nascent but growing, with over 50% of CPT codes effective since 2022. However, only a handful of these devices have reached substantial market adoption, suggesting that the medical AI landscape is still in its early stages. Such usage patterns underscore key themes regarding the deployment of AI in medicine, including clinical implementation challenges, payment, and equal access.

Successful clinical adoption of medical AI involves overcoming key implementation barriers. First, the addition of AI may require significant changes to the clinical workflow. For example, studies have detailed how the success of a diabetic retinopathy detection algorithm is mediated by deployment factors like patient consent, Internet speed and connectivity, and poor lighting conditions.<sup>66,67</sup> Another study found that the added benefit of an AI algorithm in pathology depends on the pathologist's interaction with the algorithm's outputs.<sup>68</sup> Moreover, the value of an AI algorithm to clinical practices is a function of its health care setting.<sup>69</sup> For instance, researchers have argued that clinics that use diabetic retinopathy algorithms may operate at a deficit for every patient evaluated and propose modifications to the existing payment structure to encourage adoption.<sup>15</sup> However, patients may be incentivized to visit practices that provide state-of-the-art technologies. Medical AI devices need to have a clear value proposition to health care providers to achieve widespread adoption, but the value of AI is multifaceted and context dependent.<sup>70,71</sup>

In particular, Medicare pricing for medical AI can provide insight into how AI is currently valued. The reimbursement amounts for CPT codes are determined based on three factors: physician work, practice expense, and malpractice cost.<sup>72</sup> For a given code, each factor is associated with a relative value unit (RVU) that is adjusted to account for differences between procedures. For example, a higher RVU for physician work means that the procedure involves more physician time and/or expertise. A key value

proposition of medical AI devices is their ability to reduce or remove the work burden of physicians. We find this reflected in the pricing for CPT code 92229 (diabetic retinopathy) in the CMS fee schedule. Despite having a relative value of 0 for physician work, the practice expense relative value (peRVU) for this code is 1.34, which is higher than that of its non-AI counterpart (CPT code 92228, peRVU=0.53).<sup>73</sup> This difference illustrates how the pricing of AI devices shifts some of the value typically assigned to physicians toward the costs of purchasing and operating the device itself.

Interestingly, the privately negotiated rate for diabetic retinopathy is substantially higher than the CMS rate (\$127.81 vs. \$45.36). Whereas CMS rates are designed with the aim of cost containment for taxpayer-funded programs, private insurers may negotiate rates that better reflect the actual cost or perceived value of services in a specific market. Currently, because of their Category III status, there is no Medicare pricing available for the majority of AI CPT codes. However, in private insurance data, we observed pricing for several devices. For example, AI interpretation of breast ultrasound (CPT codes 0689T-0690T) has a median negotiated reimbursement rate of \$371.55, which is comparable to the national average cost of a traditional (non-AI) breast ultrasound of \$360.<sup>74</sup> However, AI analysis of cardiac CT for atherosclerosis has a median negotiated rate of \$692.91, which is higher than the average cost range of a cardiac CT of \$100 to \$400.<sup>75</sup> As insurance companies consider reimbursements for emerging AI technologies, determining appropriate pricing remains an important step in wide AI adoption.

The payment mechanism for medical AI has implications for how it will be used and adopted. Although CPT and other procedure-based billing methods like the NTAP method are done on a per-use basis, other payment schemes may adjust for value or outcomes. For example, a recent study of reimbursement strategies has proposed forgoing separate reimbursements altogether, because the near-zero marginal costs of AI may lead to its overuse.<sup>7</sup> Alternatives include a fixed cost with discounts if certain clinical or economic outcomes are not met and a revenue-sharing deal between the AI developers and health care systems.<sup>7</sup> Other outcome-based schemes involve higher reimbursements if certain positive outcomes are demonstrated in a postmarketing study, with early examples in Europe and the United Kingdom.<sup>76</sup> Researchers have also proposed factoring in the proportion of eligible patients who receive a given service in an "access-maximizing" model.<sup>8</sup> Recently,



RadNet, a diagnostic imaging services company, rolled out a program in which patients can opt in for AI interpretation of their mammograms for a \$60 out-of-pocket fee.<sup>77</sup>

We observed that the presence of academic medical centers is a significant factor in the adoption of medical AI, as reflected in the fact that over 70% of zip codes with academic centers have at least one medical AI billing, compared with 9% in zip codes without such centers. Furthermore, metropolitan and higher-income zip codes are among those that have a higher likelihood of having AI adoption. These findings are reflective of broader adoption trends within digital health care<sup>78</sup> and are also observed in other emerging technologies like electric cars,<sup>79</sup> because areas with greater resources and infrastructure are better positioned to take on the subsequent risks and rewards. Although such differences in adoption do not necessarily imply disparities in health care outcomes,<sup>80</sup> regulators and stakeholders should consider potential obstacles to equitable access that may be in place as AI becomes a more permanent fixture of health care.

Our analysis of medical AI usage has several limitations. First, although our dataset of 16 billion claims (IQVIA PharMetrics® Plus) is representative of the U.S. patient population less than 65 years of age, it does not capture all medical claims. As such, the number of claims reported in our work only represents a fraction of total usage and should mainly be interpreted through its relative magnitude over time. Second, our analysis focuses specifically on CPT codes, which do not capture all potential types of AI usage. For example, products such as Viz.ai's large vessel occlusion detection algorithm are reimbursable under Medicare's NTAP program, but we did not capture such usage in our study. Additionally, medical AI usage in clinical pilot studies that are not reimbursed will not appear in large national databases. Furthermore, AI software included as part of a hardware system often does not include separate CPT billing. For example, GE's Edison Digital Health Platform and Critical Care Suite are included as part of their AMX and Definium x-ray systems but are not available as a separate software offering. Our analysis also does not capture the usage of medical AI devices that are billed under non-AI-specific CPT codes. For example, CPT code 77066 is used for CAD for mammograms but does not differentiate the usage of current deep learning-based approaches from older traditional models from the 1990s. As such, although new models for mammography are developed and approved by the FDA, their usage cannot be cleanly identified in claims data.

Our analysis focuses specifically on AI Software as a Medical Device, which is a subset of all medical AI. For example, proprietary laboratory analyses can often involve ML algorithms that analyze the collected data. Products like KidneyIntelX and RenalytixAI use AI in diabetes clinical care, whereas PreciseDx provides a breast cancer test. Although such products are billable under CPT codes, they are not regulated through the FDA. Another example is AI in practice management software, which is often implemented through electronic health record vendor software. For example, Epic has been reported to have about 20 predictive algorithms.<sup>81</sup> These applications are also not regulated through the FDA and are primarily paid for as part of a larger software subscription. Finally, with recent innovations in large language models, applications to areas like question-answering and clinical note-taking have emerged. However, such products are still yet to be clinically validated and regulated.<sup>82</sup>

As CPT codes are developed by the AMA for use within the United States, our analysis of AI adoption does not provide direct insight into other countries. However, broad trends in the clinical adoption of AI can be shared across countries because of the similarities of the underlying AI technology and the incentives of health care providers. For example, a recent survey by researchers in the Netherlands found that clinical use of AI is much greater in academic hospitals (57%) than in general hospitals (14%), which is reflected in our study as well.<sup>83</sup> At the same time, several factors make the United States a distinct marketplace for AI. For example, in contrast to single-payer systems, the United States has a mixture of private and public payers, in which CMS establishes a payment policy and private payers follow later.<sup>84</sup> Differences across regulatory agencies can also affect the degree of trust providers have regarding AI. An FDA approval, for instance, always requires a full clinical trial, whereas a CE mark (European Union equivalent) accepts a review of published data from existing devices.<sup>85</sup> Finally, the market for AI health care is significantly larger in the United States, with North America accounting for nearly 50% of the global market in 2022.<sup>86</sup> Such factors affect the entire AI adoption pipeline, from product investment and development to reimbursement and usage.

The small percentage that AI usage takes up relative to total billing highlights the inherent barriers to uptake and the current clinical usefulness and necessity of AI. Although AI CPT codes represent a frontier in terms of the maturity of AI, they are just one of many steps required

for the wide adoption of medical AI.<sup>87,88</sup> For example, a survey of health care providers regarding CE-marked AI devices in radiology found the main obstacles to uptake involved budgeting and information technology integration — issues that are beyond the scope of clinical validation alone.<sup>83</sup> As such, our findings reflect the fact that successful uptake of AI requires understanding the entire translational pipeline of AI technology. The usage and adoption of medical AI are the product of a complex ecosystem involving AI developers, health care providers, payers, and patients. Although the last few years have seen rapid growth in the capabilities of AI, careful consideration of forces beyond algorithmic development is required for AI models to have a meaningful clinical impact. As such, monitoring the usage and clinical adoption of medical AI is key to ensuring that these new technologies fulfill the promise of improving the quality of health care for broad patient populations.

## Disclosures

Author disclosures and other supplementary materials are available at [ai.nejm.org](https://ai.nejm.org).

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The IQVIA PharMetrics Plus claims dataset utilized in this research is available for licensing or for research through IQVIA. The insurance pricing data employed in this study are publicly accessible as part of the Transparency in Coverage regulation and can be obtained directly through the Centers for Medicare & Medicaid Services at <https://www.cms.gov/healthplan-price-transparency>.

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