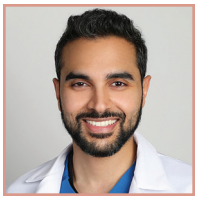
AI BEYOND THE CLINIC

How regulation and reimbursement are accelerating AI and home monitoring.



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Not only is AI taking over exam lanes, but developers are also eyeing a bigger domain—patients' homes. AI in ophthalmology has evolved from isolated image-recognition experiments into a multilayered clinical and commercial ecosystem spanning autonomous diagnostics, longitudinal clinical decision support, home monitoring, practice operations, and the early emergence of agentic automation. This progression is driven by accelerating technological innovation, growing social acceptance, and an enabling regulatory framework that defines what AI may do, how it may be deployed, and who ultimately retains clinical authority. If harnessed properly, this development could reshape population-level care for chronic eye disease and improve today's fragmented, episodic, and often poorly coordinated care model.

REIMBURSEMENT TAILWINDS IN 2025

In 2025, regulatory advances by the US FDA and CMS further supported the AI transition by expanding reimbursement for remote physiologic monitoring (RPM) and principal care management (PCM) services.[1]

Where the US FDA Draws the Line

The US FDA clarified the boundary between exempt clinical decision support (CDS) software and regulated AI medical devices.[2]

Beginning with the 2022 CDS Guidance, the agency established that software, including AI, is not regulated when it merely displays medical data and allows the clinician to independently understand the basis of the output but maintain full decision-making authority. Platforms such as Zeiss Forum Compare Reports (Carl Zeiss Meditec) and Harmony (Topcon Healthcare), which aggregate OCT and imaging data without diagnosing progression or issuing treatment recommendations, exemplify this category.

In contrast, the 2025 AI-Enabled Device Software Functions Guidance defines when AI is regulated as a medical device—namely, when it detects disease, diagnoses pathology, classifies clinical states, or autonomously recommends treatment.[3]

Regulating AI Over Time

The aforementioned framework was reinforced by the Predetermined Change Control Plan Guidance from 2024,[4] which governs how US FDA–regulated AI models may evolve after clearance. The Predetermined Change Control Plan specifies which algorithmic changes may occur without resubmission and which require renewed US FDA review. Together, these policies have created an early life cycle regulatory framework for clinical AI.

Reimbursement as the On-Ramp for Autonomous AI

On the payor side, *Current Procedural Terminology* (CPT) code 92229 (effective January 1, 2021) reimburses providers for point-of-care autonomous AI retinal imaging with automated analysis and report generation, without physician interpretation. This reimbursement milestone helped move autonomous retinal AI from pilot trials to broad deployment in primary care clinics, federally qualified health centers, and pharmacies and allows screening at scale for patients who might otherwise have limited access to eye care.

More recently, Category I CPT codes have expanded reimbursement pathways for RPM and PCM. Beyond creating new economics and incentives for practices, these codes formalize remote care extensions for Medicare beneficiaries and could accelerate the adoption of multidisciplinary, longitudinal care models.

RPM Growth and the 2025 Coding Landscape

Across the world, RPM has shifted from a niche digital health tool to a core component of chronic disease management. A recent mHealth and home-monitoring market analysis estimated that 76.7 million connected home medical monitoring devices were in use in 2023, with volumes projected to reach 140.1 million by 2028 (compound annual growth rate of approximately 12.8%).[5] The same analysis projected that RPM revenues would increase from $40.4 billion in 2023 to $77.3 billion by 2028 (compound annual growth rate of approximately 13.9%). This growth is being supported by expanded reimbursement for RPM and PCM services that enable streamlined, remote, multidisciplinary care.

For 2025, RPM codes (CPT 99453–99458) cover digital remote interventions in 20- to 30-minute monthly increments for patients diagnosed with high-risk chronic conditions such as age-related macular degeneration (AMD), diabetic retinopathy (DR), and glaucoma. PCM codes (CPT 99424–99427) address care coordination, patient education, and care management performed by clinic staff or an outsourced service under general oversight.

DR AS THE FIRST PROOF POINT FOR AUTONOMOUS AI

DR provided the first major real-world validation for autonomous AI in ophthalmology. The disease offered an ideal proving ground because screening workflows rely on standardized fundus photography and well-established grading thresholds.

The grading of DR severity is anchored in the Early Treatment Diabetic Retinopathy Study (ETDRS) scale. Key reference points include ETDRS level 35 (more than mild DR [mtmDR]), level 43 (moderate nonproliferative DR), and levels 61 to 71 (proliferative disease with retinal neovascularization).[6]

Early US FDA–Cleared Autonomous Systems

A comparison of US FDA–cleared autonomous DR systems—including mtmDR sensitivity and specificity and ungradable image rates—is provided in Table 1.[7,8]

IDx-DR. In 2018, IDx-DR (Digital Diagnostics) became the first US FDA–cleared autonomous AI diagnostic system in any medical specialty. In a pivotal trial, IDx-DR achieved a sensitivity of 87.2% (95% CI, 81.8%–91.2%) and a specificity of 90.7% (95% CI, 88.3%–92.7%) for detecting mtmDR, with an imageability rate of 96.1%. Importantly, the system issued a fully autonomous "refer" decision without physician image interpretation.[9]

EyeArt. EyeArt (Eyenuk) soon became another US FDA–cleared autonomous system. In real-world screening settings, EyeArt demonstrated 96% sensitivity and 88% specificity for mtmDR and 92% sensitivity with 94% specificity for vision-threatening DR. All eyes with an ETDRS level of 43 or higher were correctly identified as mtmDR positive. Even in primary care clinics, where imaging was often performed by nonophthalmic staff, EyeArt achieved a 97% imageability rate, and 90% of patients received a diagnostic result without pupillary dilation.[10]

AEYE-DS. In its US FDA clearance study, AEYE-DS (AEYE Health) achieved 93% sensitivity and greater than 91.4% specificity for mtmDR detection using a single image per eye from the TRC-NW400 camera (Topcon), with an imageability rate exceeding 99%.[11]

From Validation to Reimbursement

The aforementioned technological advances positioned DR as the first

TABLE 1. AUTONOMOUS DR SCREENING AI: MTMDR PERFORMANCE AND UNGRADABLE IMAGE RATES

System	Sensitivity for mtmDR	Specificity for mtmDR	Ungradable Image Rate (nonmydriatic)	Key Considerations
IDx-DR (Digital Diagnostics)	87.2%	90.7%	25.5%[7]	First-generation autonomous system; longest real-world experience; higher rate of nonmydriatic grading failure
EyeArt (Eyenuk)	96%	88%	NA	Inconsistent reporting and ungradable images noted[8]
AEYE-DS (AEYE Health)	93%	> 91.4%	< 5%	Desktop and handheld systems cleared; low rate of ungradable images; limited real-world experience to date

Abbreviations: DR, diabetic retinopathy; mtmDR, more than mild DR; NA, not available.

disease area to achieve national CMS reimbursement for autonomous AI.

FROM AUTONOMOUS SCREENING TO ASSISTIVE DECISION SUPPORT

Following the autonomous DR wave, AI development shifted toward assistive CDS rather than the replacement of physician judgment. These systems analyze longitudinal and multimodal imaging data, instead of a single snapshot, to support complex disease management in AMD, diabetic macular edema, retinal vein occlusion, and geographic atrophy.

Performance Claims and Current Use Patterns

Strong performance in the areas of OCT-based feature detection and biomarker interpretation has been reported for the following systems:

- RetinAI (EssilorLuxottica) applies longitudinal OCT and biomarker analytics, with reported performance metrics exceeding 94% to 97% for disease feature detection[12];
- Altris AI (Altris AMS) has reported cumulative accuracies of approximately 91% for OCT biomarker interpretation[13]; and
- Retinsight's automated algorithm performance reached area under the curve values of 0.93 and 0.85 for intraretinal fluid and 0.87 for subretinal fluid in the central millimeter.[14]

Why These Tools Face a Higher Bar Than DR Screening

Unlike autonomous DR systems, assistive CDS platforms do not yet carry standalone CMS screening reimbursement and typically remain embedded within bundled clinical or research workflows. Because the technology informs treatment planning over time instead of issuing a single screening decision, it faces higher regulatory and validation thresholds across multiple disease stages, devices, and imaging conditions.

BEYOND THE RETINA: ANTERIOR SEGMENT AND NEURO-OPHTHALMIC APPLICATIONS

Anterior Segment Imaging and Surgical Planning

For the assessment of angle closure and anterior segment–driven surgical planning, AI modules integrated into anterior segment OCT devices can quantify anterior chamber depth and volume, angle opening distance, trabecular meshwork–to–iris space area, iris configuration, lens position, and corneal parameters. One example is the Visulytix/CASIA2 platform (Tomey). This quantitative information can support cataract and phakic IOL surgical planning, glaucoma surgical planning, and postoperative monitoring following MIGS and other angle procedures.

Eye Movement–Based Concussion Risk Assessment

AI-enabled tracking of eye movement can be used to analyze cranial nerve–related function and generate a risk assessment score. For example, EyeBox (Oculogica) is used across sports medicine practices, neurology clinics, and eye care practices. The device presents a video stimulus while tracking eye movements and uses the collected data to estimate the likelihood of concussion.

HOME MONITORING: CONTINUOUS DATA BETWEEN VISITS

Beyond the clinic, home-based care is increasingly defined by continuous,

TABLE 2. OPERATIONAL AI IN OPHTHALMOLOGY: PLATFORM FOCUS AREAS AND KEY FUNCTIONS

Platform	Primary Focus	Key Functions
ModMed (Scribe)	EHR, RCM, workflow automation	Integrates specialty-specific EHR, RCM, analytics, and patient engagement tools, including AI-assisted documentation and workflows aligned with ophthalmology examinations and coding
CareCloud (CirrusAI)	Ambient documentation, automated charting	Uses AI-assisted, real-time documentation and charge capture to reduce after-hours work and support billing accuracy
AdvancedMD (AdvancedMD)	Practice management, coding, billing automation	Supports coding, scheduling, and billing across multisite practices to improve operational efficiency
CureMD (CureMD)	RCM	Automates coding, identifies potential claim denials, and accelerates reimbursement to reduce revenue leakage
Veradigm (Veradigm)	Predictive analytics, scheduling optimization	Uses predictive analytics for demand forecasting and scheduling to reduce no-shows and optimize staffing
WhiteSpace Health (WhiteSpace Health)	Financial and operational analytics	Provides AI-assisted insights into payer mix, billing performance, and scheduling metrics for ophthalmology and optometry practices
RevMaxx (RevMaxx)	Medical scribe support	Automates note generation and supports coding to reduce documentation burden

Abbreviations: EHR, electronic health record; RCM, revenue cycle management.

longitudinal monitoring that can detect change between visits and support earlier intervention.

Glaucoma

For glaucoma management, home monitoring is focused on expanding IOP sampling beyond episodic office measurements. The iCare Home2 (Icare USA) rebound tonometer allows patients to measure their own IOP at home.[15] Smart Lens is developing an IOP-sensing contact lens for home monitoring.[16] Similarly, ImplantData and InjectSense are developing implantable biocompatible microsensors intended to measure IOP continuously or on demand.[17] Clinical testing of these sensors is underway. If approved, the devices could generate large-scale home IOP datasets suitable for AI-enabled analytics.

Retina

In retina, home monitoring is aimed at detecting disease progression and treatment response between visits, particularly for patients with AMD. Scanly (Notal Vision), a home OCT system, supports remote structural monitoring and analytics of OCT biomarkers associated with disease progression and treatment response.[18] Other approaches emphasize functional change. For example, ForeseeHome (Notal Vision) provides vernier acuity testing to support the early detection of metamorphopsia.[19]

EXPANDING HOME TESTING

Some platforms aim to provide at-home testing that can be deployed across multiple conditions and incorporated into long-term care workflows. RemoniHealth offers a suite of functional tests for AMD, glaucoma, DR, thyroid eye disease, and other indications[20]:

- **Macular function.** Macustat provides on-demand self-assessment of visual acuity, Amsler grid performance, and hyperacuity perimetry using consumer devices without dedicated hardware.
- **Visual field and acuity.** Peristat supports home perimetry for visual field testing, and Accustat supports visual acuity testing.
- **Ocular surface and motility.** Photostat uses AI-enabled tracking to assess ocular surface and motility features.
- **Care integration.** RemoniHealth has also built an enterprise platform for remote monitoring and care management that recently surpassed 100,000 RPM and PCM encounters.

DRY EYE: AI-ENABLED BEHAVIORAL SUPPORT

Emerging AI solutions in the dry eye space include consumer-facing tools aimed at symptom mitigation. The Blinkr app (Blinkr) offers an at-home or workplace approach to dry eye symptoms associated with computer use. It monitors the user's blink rate and provides a notification when the rate falls below a threshold. The company reports that, over time, the app retrains blink behavior and alleviates symptoms.[21]

OPERATIONAL AI IS SCALING FASTER THAN CLINICAL AI

Some of the most immediate and scalable effects of AI in ophthalmology are occurring in practice operations rather than diagnostics. Tools are being used to streamline electronic health record documentation, revenue cycle management, coding, billing, scheduling, and ophthalmology-specific analytics across a range of platforms and vendors (Table 2).[22-28]

Although home monitoring is extending clinical data capture, the most widespread real-world AI deployment in ophthalmology is occurring operationally. Automation of documentation, billing, scheduling, and analytics is advancing faster than frontline clinical AI tools. Because the former typically pose a lower direct risk to patient safety, regulatory oversight is often lighter, which may accelerate adoption and enable future integration with more advanced agentic AI systems.

Agentic AI

Agentic AI represents the frontier of automation because it is designed to plan and execute multistep workflows across domains rather than to complete isolated tasks.

Patient journey workflows. Sully.ai markets AI agents spanning intake, scheduling, documentation, coding, and follow-up.[29]

Revenue cycle workflows. FinThrive applies agentic principles to automate claims submission, denial detection, appeals, and revenue optimization with minimal human oversight.[30]

Why Fully Agentic Clinical AI Has Not Arrived Yet

No fully agentic clinical platforms currently exist. Available systems remain partially autonomous, reflecting a practical constraint: as autonomy increases, regulatory scrutiny and clinical risk increase. As regulatory science evolves alongside algorithmic capability, fully agentic clinical AI may become an inevitability rather than a theoretical possibility. ■

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