

Expanding access to cardiac ultrasound through AI-guided digital technology

An integrated evidence plan (IEP) case example



About Caption Health's Caption Guidance™

[Caption Health](#), now part of GE HealthCare, revolutionized the diagnostic imaging landscape by developing the first FDA-authorized AI software for cardiac ultrasound, Caption Guidance™. It enables healthcare providers without prior ultrasound experience to perform diagnostic-quality echocardiograms, addressing the national shortage of cardiac sonographers. By achieving FDA De Novo clearance and securing New Technology Add-on Payment (NTAP) status from CMS, Caption Health expanded access to life-saving diagnostics for Medicare patients. This case highlights Caption Health's strategic approach to regulatory authorization, clinical validation, and commercialization, demonstrating how effective regulatory navigation and rigorous clinical validation by Caption Guidance drive the broader adoption of AI in medical imaging.



Let's explore Caption Health journey through the lens of the Integrated Evidence Plan for digital health technologies toolkit - Stage C, highlighting the process, key decisions, and concepts that shaped their success.



Stage C: Commercial strategy & market access

- **Market landscape analysis:** Caption Health analyzed existing reimbursement policies and identified gaps in coverage for AI-guided cardiac ultrasound.
- **Craft targeted value story:** The team developed messaging emphasizing Caption Guidance™'s ability to address workforce shortages, improve diagnostic accuracy, and reduce costs. Addressed the need for scalable, cost-effective cardiac diagnostics to meet the demands of underserved and high-risk populations.
- **Commercialization strategy:**
 - Focused on hospital systems, primary care, and rural health clinics.
 - Focused on [securing CMS New Technology Add-on Payment \(NTAP\) status](#) by demonstrating positive economic impact, ensuring hospitals recovered costs when adopting Caption Guidance.
 - The strategy also included developing a mobile diagnostic service.
- **Reimbursement pathway:**
 - Caption Health secured CMS NTAP designation, reimbursing hospitals up to

\$1,868.10 per admission for Medicare patients across 461 DRGs involving heart failure, stroke, and other cardiac conditions.

- NTAP payments cover the use of Caption Guidance when costs exceed standard DRG payments, reducing financial barriers and accelerating hospital adoption.
- **Go-to-market (GTM) and scaling:**
 - **Direct-to-hospital sales:** Partnered with hospitals and healthcare systems for in-house adoption.
 - **Mobile service:** Established and launched a full-turnkey mobile diagnostic service, [Caption Care](#), operating as a separate entity, enabling in-home or in-clinic cardiac imaging to support population health screening and evaluation for structural heart disease in vulnerable populations with Heart Failure risk factors.
 - **Focus on underserved areas:** Targeted primary care, value-based care providers, rural hospitals, and home health services, to increase access to diagnostics in underserved regions to target earlier disease detection and management.
 - Identified key Medicare NCD and LCD MAC policies that may influence coverage and reimbursement of professional or technical fees. Explored broader payor medical and benefits policies around outpatient reimbursement for POCUS echocardiograms.
- **Long-term success:**
 - In 2023, [GE HealthCare acquired Caption Health](#), integrating Caption Guidance into GE HealthCare's \$3 billion ultrasound division.
 - GE HealthCare's scale is expected to drive broader adoption, expanding market reach globally and accelerating adoption across the ecosystem.



By the end of stage C, Caption Health had:

- ✓ Secured a FDA's new [Predetermined Change Control Plan \(PCCP\)](#) grant, enabling software updates without reapplying for clearance
 - ✓ Successfully secured NTAP designation from CMS reducing initial financial barriers for adoption.
 - ✓ Developed a structured reimbursement strategy, engaging key payors and hospital leaders to shape coverage decisions and ensure financial viability.
 - ✓ Launched a full-turnkey mobile diagnostic service known as
- ✓ **Regulatory strategy**
 - ✓ **Reimbursement pathway**
 - ✓ **Reimbursement pathway**
 - ✓ **Business**

Caption Care, operating as a separate entity, to increase access to cardiac imaging, particularly in underserved areas.

- ✓ Expanded commercial adoption by integrating Caption Guidance™ into GE HealthCare's ultrasound division, leveraging GE's global market reach.
 - Vscan Air™ SL with Caption AI™
 - Venue™ with Caption Guidance™

priorities

- ✓ **Business priorities**