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Artificial Intelligence and Innovative Clinical Devices: Who is Paying for These Technological Advances?

By Chris Swenson

In the healthcare industry, there is a continuous increase in the number of technological innovations being developed. These advancements are utilized across various clinical settings like imaging and operating rooms to support and ancillary settings like pharmacies, back-office billing and claims, scheduling systems, and administration. The applications vary greatly from surgical instrumentation and clinical assets to machine learning and automated intelligence (AI) programs which integrate with EHR platforms and other software. These technologies can aid in scheduling staff and clinical space, medication administration, inventories, imaging identification, and more. The benefits of these advancements are numerous including error mitigation, improved clinical outcomes, and more direct and accurate record-keeping and financial reporting. It's no secret the role of innovation in healthcare with start-ups and established companies alike heavily investing in these technological advancements to make improvement to the healthcare space. It is also easy to see why these innovative solutions typically come with such a high price tag. With financial reporting margins tightening and the industry operating in a new transparent pricing system, how can hospitals, ASCs, HOPDs, and all other areas of service be compensated for their efforts to achieve better outcomes?

The New Technology Add-On Program (NTAP)

In 2001, the Centers for Medicare & Medicaid Services (CMS) introduced the New Technology Add-On Program (NTAP) to help close this financial gap and encourage the use of innovative therapies and technologies. For products that meet their specific criteria, CMS provides an additional payment to the standard Medicare Severity Diagnosis-Related Group (MS-DRG) payment amount. The criteria the technology must meet are as follows:

- must be no more than 3 years available to market
- must carry a level of cost efficiency
- must be evidence identified of better clinical outcomes

The additional payment typically equates to no more than 65% of the case cost of the technology. Early adopters of innovative technologies must submit an application to have the technology added for NTAP. Once CMS approves the technology, it is assigned a code that covers any and all vendors of the same technology. CMS reviews NTAP technologies each fiscal year and will extend or discontinue technologies from the program based on the original criteria. Most products "age out" after 2-3 years on the list based on initial availability dates. The NTAP changes can be found in the Federal Register when the CMS final rule changes are released.

What happens once an approved technology is 2 to 3 years on the market and no longer meets the newness criteria? At that point, CMS will discontinue the technology for the next fiscal year's list of NTAP payments. Should we assume at this point the service provider begins to cover the full technology cost? Not exactly. CMS routinely reviews and recalibrates MS-DRG rates based on regular claims data. This rate review does produce a 2-to-3-year lag in accurate price reflection, intentionally aligning with the CMS stance that technology will age out of the newness criteria in that time and the standard MedPAR rates should more accurately reflect the current price of that MS-DRG to include additional technology spend.

Technologies Previously Approved Through CMS Final Rule

As previously stated, these innovations are seen widely across the healthcare continuum. Let's take a deeper look in recent years and narrow our discussion to specific technology like automated intelligence (AI) used within imaging platforms. AI can be used with imaging to achieve quicker detection results and decision-making and fewer diagnostic errors. Specifically, within the Neurosciences and Cardiovascular service lines, many applications exist where AI is integrated to better identify blockages, embolisms, and general abnormalities. The technology skips antiquated communication protocols and directly notifies surgical specialists and on-call teams to gather for interventional needs.

Beginning in 2018, there were two primary companies that introduced a product that aids in identifying large vessel occlusions (LVOs) in stroke patients through AI technology. This technology was approved for NTAP and hospitals utilizing this technology were receiving $1,040 per case. In the CMS FY23 IPPS final rule, this technology had been discontinued from the NTAP list due to the newness criteria. Upon review of Medicare payment rates over those years the appropriate interventional stroke payments for MS-DRGs 23 and 24 has increased respectively $700-$1,000 from FY21 to FY22, and $1,100-$1,900 from FY22 to FY23. With such increases through FY23, it does appear that

hospitals are recouping the NTAP payments in the base DRG amounts. We must also account for the fact that CMS rates have increased in general over these years and other principal diagnosis' fall under these DRGs (ie. Epilepsy with neurostim) that may or may not require the technology. Therefore, analysis and assessment of financial and operational metrics and margins for specific procedures or service lines will always be encouraged to measure cost impacts to a specific individual performing site.

DRG Rate Changes for Craniotomies with Device (incl. Thrombectomy)

DRG	DRG Description	FY21	FY22	FY23	FY24
023	CRANIO W DEVICE OR CHEMO IMPLANT OR EPILEPSY STIM W MCC	$36,394	$37,402	$39,315	$39,691
			3%	5%	1%
024	CRANIO W DEVICE WO MCC	$25,276	$25,975	$27,087	$26,528
			3%	4%	-2%

Another example of a technological innovations previously approved by CMS and included on the NTAP list for add-on payments was Intravascular Lithotripsy Systems (IVL). IVL is a novel approach of delivering vaporizing fluid that generates sonic pressure waves (shock waves) that interact with severely calcified plaques. Specifically, lets look at Coronary IVL in Percutaneous Coronary Intervention (PCI) procedures which was approved for add-on payment in FY2022 and FY2023, and now excluded with the final ruling for FY2024. Medicare rates for PCI have historically been coded between 6 sequential DRGs 246-251. Each DRG differing by distinction of with or without stent, stent type, and number of stents. DRGs 250-251 are procedures without stenting and are not relevant here. The maximum approved add-on payment for IVL was previously $3,666. We are seeing a different picture play out for these DRGs. We had minor increases to the stented DRGs 246-249 during the period approved for NTAP, not near the $3,666 that will no longer be paid by NTAP. That said, with the recent FY2024 final rulings we see a complete reorganization of PCI DRGs. The previous DRGs for stented procedures, DRG 246-249, have been deleted making room for new PCI codes that are specific to distinguishing Intraluminal and IVL procedures and PCI with or without an intraluminal device. In the new IVL specific DRGs 323-325, we do appear to see rate increases representative of the use of the technology no longer approved for NTAP.

DRG Rate Changes for Coronary Interventions with Stenting (Incl. IVL)

DRG	DRG Description	FY21	FY22	FY23	FY24
246	PCI W DES W MCC OR 4+ VES/STENTS	$20,090	$20,603	$20,547	
			3%	0%	
247	PCI W DES W/O MCC	$12,779	$13,012	$13,098	
			2%	1%	
248	PCI W NDES W MCC OR 4+ VES/STENTS	$20,400	$20,853	$20,646	
			2%	-1%	
249	PCI W NDES W/O MCC	$12,079	$12,356	$12,462	
			2%	1%	
321	PCI W/ INTRALUMINAL DEVICE W/MCC OR 4+ ARTERIES				$20,127
322	PCI W/ INTRALUMINAL DEVICE W/O MCC				$12,767
323	CORONARY INTRAVASCULAR LITHOTRIPSY W/ INTRALUMINAL DEVICE W/ MCC				$28,987
324	CORONARY INTRAVASCULAR LITHOTRIPSY W/O INTRALUMINAL DEVICE				$20,785
325	CORONARY INTRAVASCULAR LITHOTRIPSY W/ INTRALUMINAL DEVICE W/O MCC				$18,514

NEW

The cardiovascular space is ever evolving technologically and a good amount of approved NTAP payments making a significant financial impact are out of technological innovations in the cardiac service lines. Another example of an approved innovation is the Thoraflex Hybrid Device, designed to repair aneurysms and dissections of the aortic arch. With a CMS estimated annual impact of over $18M reimbursed in NTAP payments, this product's add-on payment approval continues for FY2024 at a maximum payment of $22,750. Another breakthrough technology previously approved and continuing through FY2024 is the Gore Tag Thoracic branch Endophresis device, designed to repair the descending thoracic aorta (the largest artery in the chest). CMS has approved a maximum add-on payment of $27,807 and estimates an annual impact of almost $11M in reimbursements from NTAP for this device. These are just two current examples of the financial impact that otherwise would remain unseen for 2-3 years of CMS MedPAR rate reviews without the New Technology Add-On Program.

New Technologies Applied For FY2024 NTAP

CMS estimates that the estimated total impact of New Technology Add-on Payments for FY2024 is almost $495.5 million. Approximately $131 million of that impact is from technologies approved for NTAP prior to FY2024, leaving more than an estimated $364 million in newly approved add-on payments beginning in FY2024. So, what sort of technological advancements can we expect to see receiving add-on payments with the recent CMS FY2024 final rulings?

Implantable Cardioverter Defibrillators (ICDs)

An innovative device receiving on the final rule NTAP product list for 2024 is the *Aveir leadless pacemaker System* by Abbott's *Cardiac Rhythm Management* division. The *Aveir System* is a first-to-market programmable system offering single-chamber as well as dual-chamber pacing therapies. The Aveir System is installed using a minimally invasive catheter-based procedure, eliminating complications of the surgical pocket and transvenous leads of previous pacing systems. Leadless pacemakers are designed to be retrievable as dictated by clinical circumstances and the *Aveir System* can provide intra-operative mapping capabilities allowing assessment of the target area and potential repositioning of the device to avoid repeat procedures. Approximately 80% of U.S. patients requiring permanent pacemakers require dual-chamber pacing so the dual-chamber device is estimated to be much more impactful. The devices respectively are approved for $10,725 for a single-chamber device, and $15,600 for a dual-chamber device and an estimated annual aggregate impact of almost $38 million.

The *Aveir Leadless Pacemaker (dual-chamber) System* by Abbott is proposed to be consistent with other dual-chamber pacing systems procedure codes, indicating coverage under ICD-10 Diagnosis Code I49.9 Cardiac arrythmia, unspecified.

Diagnostic Software For Structural Heart Assessment

EchoGo Heart Failure 1.0 is a software developed by Ultromics Limited as an A.I. diagnostic aid for patients undergoing routine echocardiography. This software takes in a two-dimensional echocardiogram with a 4-chamber view and assesses the video using an artificial intelligence neural network to provide the interpreting physician with information specifically designed to detect heart failure with preserved ejection fraction (HFpEF). According to Johns Hopkins Medicine, HFpEF accounts for nearly half of the 6.6 million cases of heart failure annually in the United States. CMS has approved a maximum add-on payment of $1,024, and an estimated annual impact of $20 million in FY2024.

EchoGo Heart Failure 1.0 will be used to identify indications of many diagnoses covering ICD-10 Diagnosis codes for heart failures, heart diseases, STEMI, valvular stenosis, and myocarditis. A full list of included codes to be applied for can be found on the Public Application Summary for this product, NTAP application *NTP2210172L1HN*.

Coronary Artery Bypass Grafting (CABG) Surgery Support

Not all news is good news in the Coronary Artery Bypass Grafting (CABG) product line. Below are two innovative technologies to CABG procedures whose applications were withdrew before a FY2024 final ruling was made. These technologies may still be increasingly prominent in the market but will not be receiving an add-on payment in FY2024.

The *VEST* by Vascular Graft Solutions is an innovative device made of braided cobalt-chromium alloy that can be fitted over the saphenous vein when used as a bypass conduit in CABG surgery. This is the only technology proven to prevent vein graft failures due to graft kinking and vein graft disease (intimal hyperplasia). *VEST* ultimately reduces clinical events such as PCI, re-do CABG, myocardial infarction, angina, and death associated with vein graft failure.

The *Duragraft* by Marizyme, Inc. is another vein graft treatment for CABG surgery. *Duragraft* is a wetting solution and replacement for normal saline or other salt solutions like Plasmalyte and Lactated Ringers for the harvested vein and arterial grafts until time of grafting. *Duragraft* is two solutions mixed at that time of use which protects the vein graft from vascular endothelial damage reducing ischemic injury and other vein graft failures that result in repeat revascularization or myocardial infarction.

There are many other products approved for the FY2024 NTAP list, including multiple pharmaceuticals, Orthopedic implants, and extension devices. Every Fiscal Year, these product applications are posted publicly for transparency. The full list of New Technology Add-On Payment Application Summaries can be found through the Medicare Electronic Application Request Information System (MEARIS), found here: *https://mearis.cms.gov/public/publications/ntap*.

For more information on the proposed updates for 2024, contact Corazon at 412-364-8200.

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Web Sources:

2022-16472.pdf (govinfo.gov)

FY 2023 Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital Prospective Payment System (LTCH PPS) Final Rule — CMS-1771-F | CMS

2023-16252.pdf (govinfo.gov)

MEARIS™ (cms.gov)