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OCTOBER 2020
Vol 2.9

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Impulse Dynamics:
Using Breakthrough Status to Help Increase Reimbursement

One of only a handful of companies to be approved for this year's New Technology Add-on Payment program, Impulse Dynamics reveals how achieving Breakthrough technology status can help ease a company's route to added reimbursement, and how it benefited from the MACs' recent positive reversal on Category III code coverage.

Enabling reimbursement to keep pace with technology innovation has been a longstanding challenge for the medtech industry. Payors in the US, sometimes including CMS, have typically lagged well behind the introduction of newly FDA-approved/cleared products, resulting in hospitals being reluctant to purchase these devices, clinicians' being slow to adopt them, and patients—particularly those relying on Medicare—often being denied the benefits of these advanced technologies. To help address this situation, 20 years ago Congress enabled CMS to provide additional incremental reimbursement for new technologies by creating the New Technology Add-on Payment (NTAP) program.

Nonetheless, despite CMS' efforts over the ensuing two decades to work around the edges to improve NTAP, industry remained concerned that the program was failing in its goal to deliver new technologies to patients in a timely manner. More recently, however, the agency has adopted what could be the most significant shift in administering NTAP by effectively linking the program with FDA's Breakthrough device designation. Essentially, this enables companies that have achieved Breakthrough status to automatically meet certain NTAP requirements, thereby making it easier for them to qualify for the added reimbursement program.

Impulse Dynamics was one of only two device companies (**CVRx Inc.** being the other) that utilized their FDA Breakthrough designation to help achieve NTAP status this year. This example of cooperation on the part of CMS and FDA reflects a level of collaboration long sought by industry and perhaps heralds the growth of inter-agency programs that can increase efficiency and timeliness in both regulatory and reimbursement pathways.

NTAP's Ups and Downs

The NTAP program was created to fill the gap that exists in the Hospital Inpatient Prospective Payment System (IPPS) for new devices and drugs that often exceed the allowable cost of existing products. Without getting too far into the regulatory weeds, the IPPS, which was created in 1983, launched a preset prospective payment system for in-hospital procedures structured according to diagnosis, what

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we have come to routinely refer to as DRGs (the full title being Medicare Severity-Diagnosis Related Group or MS-DRG). Even though CMS updates the DRG payment levels annually, the agency bases those updates on claims data that it collects over a two-to-three-year period. The result is what the industry refers to as a payment lag between the allowable DRG and the current cost of treating a patient with state-of-the-art devices and drugs. NTAP was created to account, at least partially, for that payment lag by increasing the allowable payment for new products to encourage their use so that Medicare patients would have access to the latest treatments.

CMS requires that technologies meet three standards to qualify for NTAP status: the technology must be new; the cost of the procedure (including the new product) must exceed that of the covering DRG, making that current payment rate inadequate; and the new device or drug must represent a substantial improvement over existing products. Upon meeting those requirements and being eligible for an NTAP, the payment rate for a device or drug could be the lesser of half the amount by which the costs exceed the current DRG, or half of the costs of the new product. That new NTAP rate will extend through the two-to-three-year period until the DRG is next adjusted.

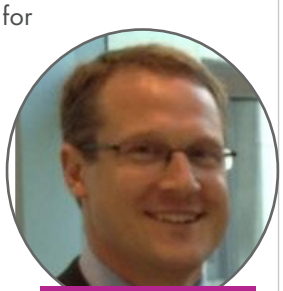
The NTAP program, however, has fallen short on two counts. First, the process has not kept pace with the rate of new technology development. According to CMS data through 2018, the agency only received a total of 72 device NTAP applications, of which 27 were approved. That is only a small fraction of the number of in-hospital devices approved or cleared by the FDA during the same period. (The FDA doesn't break down devices according to in-hospital usage, preventing any determination of exact numbers.)

The other NTAP shortcoming is on the payment front. Comparatively speaking, the NTAP reimbursement level falls short of other technology payment programs, including the Medicare outlier payments, which can reach 80%, and the transitional pass-through payments for out-patient services (the Medicare Outpatient Prospective Payment System or OPPS), which is considered the out-patient version of NTAP.

CMS' decision to allow companies to apply their FDA Breakthrough status to meet applicable NTAP criteria can help address the former shortcoming by encouraging more firms to apply since they have already met certain existing standards. (*See "Medicare's Breakthrough Coverage Proposal: Innovation, Evidence, and the Valley of Death,"* Market Pathways, *September 18, 2020.*) As a point of comparison, the Breakthrough Devices Program, which was created by the 21st Century Cures Act in late 2016 (superseding the Expedited Access Pathway launched in 2015 and the Innovation Pathway piloted in 2011), already has accepted more than 300 products. It is also worth noting that Breakthrough status could potentially help a company meet two of the three NTAP requirements: newness and substantial clinical improvement, which are the most common reasons for which CMS rejects NTAP applications. For Impulse Dynamics, the intersection of the two programs couldn't have come at a more opportune time.

20 Years in the Making

Coincidentally, the timelines of both Impulse Dynamics and the NTAP program largely overlap. The company was founded in 1998 by renown Israeli medtech inventor and entrepreneur Professor Shlomo Ben-Haim, the founder of, most notably, Biosense (now part of J&J's Biosense Webster electrophysiology mapping and ablation company), as well as Spectrum Dynamics, X-Technologies, Radiancy and InStent. Impulse Dynamics pioneered the science of cardiac contractility modulation (CCM) therapy for patients with moderate to severe heart failure (HF) who are not responsive to drug therapy.



CHRIS BROOKS

Ben-Haim developed the *Optimizer Smart* device, which is a pacemaker-sized implant that is inserted by an electrophysiologist (EP) through a minimally-invasive procedure that can be performed in one hour in an out-patient setting similar to that for an ICD (implantable cardioverter defibrillator) with little need for additional physician training. The device delivers electrical impulses to the heart that improve the muscle's contractility. Chris Brooks, Impulse Dynamics' director of health economics, explains, "Our indicated population is really a group of heart failure patients

who have pretty limited therapy options. They basically have to fail what healthcare providers call guideline-directed medical therapy to qualify for our device."

This patient population represents a kind of gray area within the growing heart failure cohort. They often appear not to be symptomatic while resting, but a task as simple as going up a flight of stairs or walking around the block can be a struggle, resulting in severe shortness of breath and fatigue. However, they are nowhere near sick enough to qualify as candidates for a more serious invasive therapy such as an LVAD (left ventricular assist device) or a heart transplant.

Impulse Dynamics received PMA approval in March of 2019, having previously received a CE mark for the *Optimizer* in 2016. The company initially received approval for a first-generation, three-lead device (two in the right ventricle and one in the right atrium), but is currently commercializing a next-gen two-lead device that only uses ventricular leads and was approved in October 2019.

Upon receiving regulatory approval, Impulse Dynamics benefited from having existing ICD-10 codes covering its technology for in-patient use and Category III CPT codes for out-patient treatment. "We are the only device on the market that fits into these codes for CCM as no other company is FDA-approved to do what we do, and as far as we know, there is nobody else that has similar technology in the pipeline," says Chris Brooks. "So we're really building a market, both on the commercial side, but also on the reimbursement side in terms of payor access and converting those Category III codes to Category I codes. We're the only ones in the space, which for a small company can present both opportunities and challenges."

Removing the Curse of Category III Codes

The downside of being the only company in the CCM space is that effectuating coding changes can be a heavy load for a small company to carry, as opposed to a large strategic armed with greater reimbursement resources. Brooks points out that he and a colleague constitute the entire market access team at Impulse Dynamics, doing 90% of the work with the rest handled by outside consultants.

The immediate reimbursement challenge for the company upon receiving regulatory approval was that the seven local MACs (Medicare administrative contractors) that cover the US all had policies against covering devices with Category III codes. Chris Brooks explains that Impulse Dynamics was in a situation where it was forced to work with each of the MACs, rather than approach CMS for a single national coverage decision (NCD). "CMS has stated a preference for allowing the MACs to make policies that reflect the local practice of medicine and will only intervene at the national level if manufacturers and the regional contractors are unable to reach agreement," he notes. Another advantage to working with the MACs is that seeking an NCD from CMS is an all or nothing proposition. "It's great if it works, but if it doesn't, you're back at square one and probably have to start a new clinical trial," says Brooks.

Impulse Dynamics' reimbursement strategy was also at a tipping point driven by where its procedures were being performed. "When you look at the nature of our procedure, it is performed in one hour or less, and is very conducive to an out-patient setting," Chris Brooks explains, "but when we were approved, we couldn't get Medicare to pay for a case in the out-patient setting, which was a massive barrier."

While there was no restriction on reimbursement for an in-patient procedure, the challenge for Impulse Dynamics is that the in-patient setting is not always an ideal option for a patient, despite relatively high rates of hospitalization for heart failure patients. Brooks points out "If a patient is in the hospital with heart failure, most physicians' primary objective is to get them to a point where they can be discharged and aren't looking to perform a procedure on a hospitalized patient," adding also that "A lot of people see ours as primarily an elective procedure."

So while the physicians were telling the company that they wanted to perform the procedure on an out-patient basis, the facilities (initially hospital out-patient centers, transitioning in the future to ambulatory surgical centers [ASCs]) were reluctant to embrace the procedure since it would be difficult to obtain reimbursement. Those difficulties had nothing to do with *Optimizer* specifically, but rather resulted from the general prohibition against reimbursement for Category III products.

As a result, Impulse Dynamics proceeded to file seven reconsideration applications, one with each of the MACs. "We believed that was the right strategy since we were dealing with blanket Category III policies, not with decisions that directly addressed our therapy," says Brooks. The company felt it could reasonably rely on its solid foundation of clinical literature and the fact that its device was being used to treat an under-served population of Medicare patients. In Brooks' view, "We felt confident going to the MACs to address this on a local level because we didn't really feel as if the issue had risen to the level where we could only solve it using CMS' NCD process."

Saved by the Bell

All of the MACs accepted Impulse Dynamics' reconsideration applications as valid, a determination that they are statutorily required to make within 60 days of submission. However, with these seven applications pending, in July 2020, all but one of

the MACs ended up retiring their prohibitions against covering Category III products. The basis for this determination was a provision in the 21st Century Cures Act that prohibits coverage policy based on coding categories. Even though the law had been passed a few years before the company's applications were submitted, it took that long for the MACs to revise their policies.

The decision by the MACs to remove the Category III prohibition obviated the need for them to act on Impulse Dynamics' reconsideration applications and removed the impediment to the company being reimbursed for out-patient procedures. As Brooks notes, "Those policies had been a major obstacle for new technologies for a long time and the change was a welcome development for all innovators in the medtech space."

In the meantime, while the company was going through this process with the MACs, it had also applied for and received Breakthrough designation from FDA and obtained outpatient pass-through approval. That had set-up a kind of strange tension between being rewarded as an innovative technology on the one hand by FDA, but being told by the MACs that they wouldn't reimburse because the product had a Category III designation. The MACs' recent decision eliminates that tension for all innovative products and provides greater harmonization between the regulatory and reimbursement bodies.

Impulse Dynamics will continue to work to change its coding status from Category III to Category I in order to improve its overall reimbursement standing, particularly for physician payments. That process requires working through the clinical committees of the American Medical Association that manage the CPT process, but the issue no longer stands in the way of the *Optimizer* being reimbursed for use in out-patient facilities. According to Brooks, "It's not the same as having a coverage policy; it is often referred to 'silent coverage', which is pretty common for innovative cardiovascular technologies." That essentially means there is no policy at the MAC or CMS level that says they will not cover the company's device. "Physicians can use their judgment on what technology is medically necessary predicated on language that appears in the Social Security Act, and that is a big deal for us," he adds.

Breakthrough Boosts NTAP

While Impulse Dynamics was working on solving its Category III issue, the company also, as noted, applied for and received both transitional pass-through payment and Breakthrough device approval. And while Impulse Dynamics was approved for the transitional pass-through, it encountered another reimbursement anomaly. Currently, most *Optimizer* procedures are performed in hospital out-patient settings even though they are well-suited to also be done in ASCs, where they qualify for payment under the transitional pass-through.

The problem, according to Chris Brooks, is that "there is almost no historical precedent for surgery centers paying pass-through payments, so we're trying to reach an agreement with them on how they will value procedures that require our device. It's tough for a provider to offer a procedure when they don't have clarity on how they are going to be reimbursed for it." Hospital out-patient units know what they will be paid for this procedure, but the ASCs don't. As a result, the company is actively working on that issue with some of the MACs, as well as with CMS, to figure out whether there is a way to standardize how pass-through payments are valued in the ASC setting so that physicians have the ability to offer these types of procedures in those facilities. "The irony," Brooks notes, "is that we are payable in the surgery center setting, so the question isn't are we payable; it's how we are valued."

As part of its reimbursement strategy, Impulse Dynamics also applied for NTAP status (which covers in-patient procedures for the *Optimizer* device), which is administered by CMS' acute care division. A big boost for the company in this effort came from having already received FDA Breakthrough status. "When you have Breakthrough designation from the FDA, you automatically meet the substantial clinical improvement criterion for NTAP, which is almost always the hardest of the three criteria to meet," Brooks explains. "That actually made the application process a lot simpler for us because rather than needing to substantiate clinical improvement with physician testimony and clinical trial data submissions, we could just submit the evidence we presented to FDA for approval under the Breakthrough statute." With its Breakthrough status coming quickly on the heels of its PMA approval, the company was also able to easily satisfy the NTAP newness requirement, further simplifying the application process.

Even though the in-patient market is not likely to be a major commercial focus for Impulse Dynamics, Brooks considers NTAP status, which became effective on October 1 as part of the program's annual implementation process, to be important both in providing added revenue and in what he calls "the general spirit of trying to bring more innovation to Medicare beneficiaries." He points to the cooperation between FDA and CMS in linking the Breakthrough and NTAP programs as signs of both agencies recognizing the importance in ensuring that Medicare patients have access to state-of-the-art technologies.

In Chris Brooks' view, "For us, having Breakthrough designation is a really big deal and it is a good sign that CMS, in administering NTAP, recognizes what a company has to go through to obtain that designation in reviewing applications for incremental payments in the future. So hats off to both CMS and FDA for acknowledging the gauntlet that a company has to run to obtain Breakthrough designation and obtain additional reimbursement, because for medtech companies trying to bring innovative products to market, both are very meaningful."