



Summit on
**Reimbursement Strategies
for Focused Ultrasound**

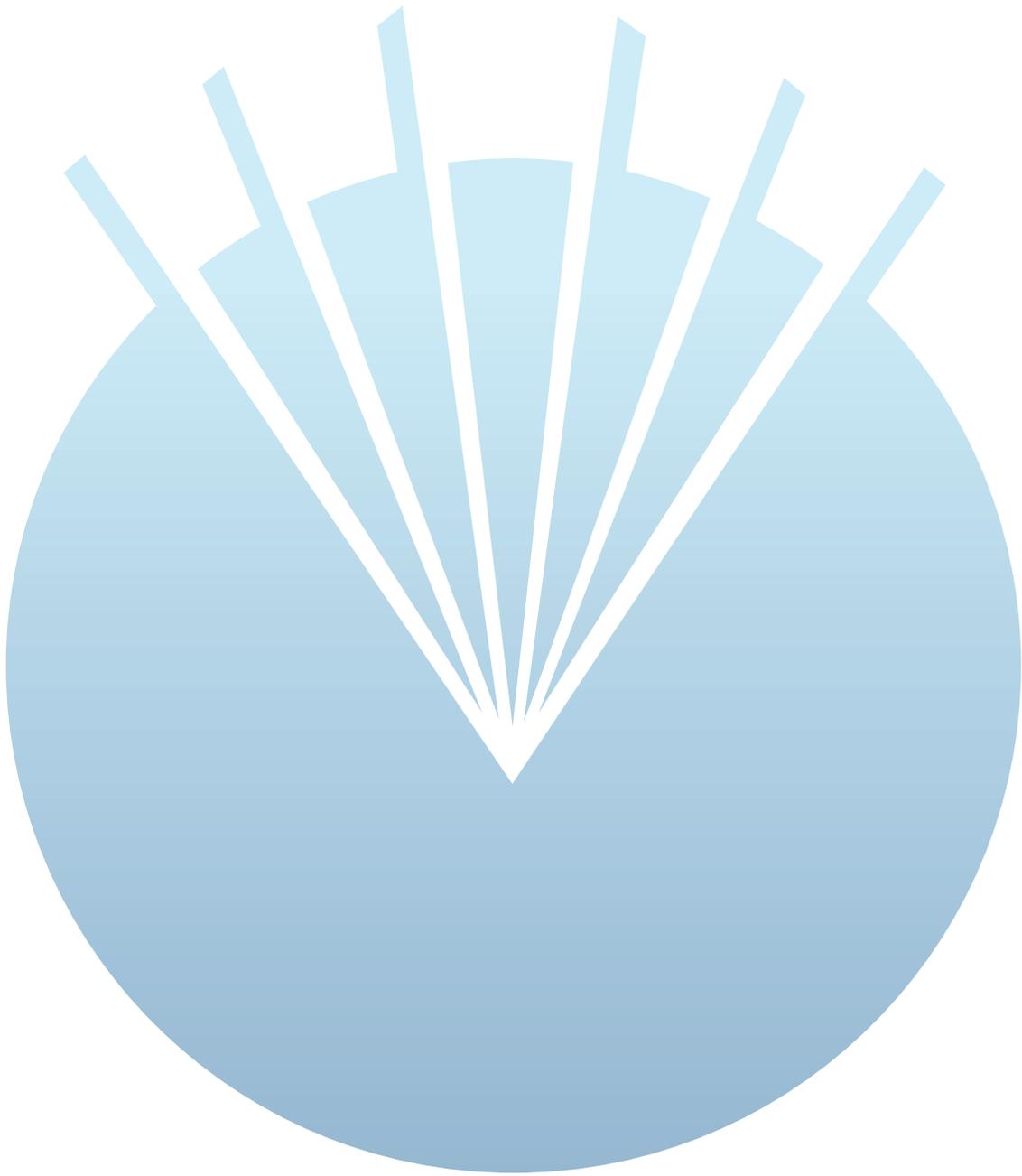
Meeting Summary
11 March 2020

Advanced Medical Technology Association Offices
701 Pennsylvania Ave, NW, Suite 800
Washington, DC

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Summit Summary

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Executive Summary

The Focused Ultrasound Foundation and the Advanced Medical Technology Association (AdvaMed) co-hosted a Summit on Reimbursement Strategies for Focused Ultrasound on March 11, 2020. The purpose of the meeting was to make progress toward creating a framework for focused ultrasound reimbursement and coverage. Focused ultrasound is an early-stage, disruptive, noninvasive therapeutic technology that has the potential to improve the lives of millions of patients with a variety of medical disorders by providing an alternative, or a complement, to existing treatment approaches.

The summit convened the four focused ultrasound device companies that manufacture U.S. Food and Drug Administration (FDA) cleared devices to discuss their experiences with obtaining treatment reimbursement, identify challenges and barriers, and brainstorm ways to address them.

Specifically, attendees included industry representatives from EDAP-TMS, Insightec, Profound Medical, and SonaCare Medical, along with representatives from AdvaMed, the Medical Imaging & Technology Alliance (MITA), ADVI, Dobson DaVanzo & Associates, and the Foundation. The summit's overarching goals were to educate participants about key reimbursement topics, share experiences, and outline the most promising pathways for achieving better reimbursement across the field of focused ultrasound. Although the focused ultrasound field and the Foundation have made great progress in overcoming challenges with the FDA approval process, there is not yet the same success with the Centers for Medicare and Medicaid Services (CMS) and reimbursement in general. The Foundation is exploring how it can do more to help support manufacturers' reimbursement efforts, in collaboration with partners like AdvaMed and MITA.

The summit's presentations provided a high-level overview of several of the many components that affect reimbursement: FDA approval pathways, the complex role of charges and costs, and coding. After lengthy discussion, attendees identified some next steps that might help companies achieve reimbursement sooner and allow patients access to innovative focused ultrasound treatments. Attendees recommended the following paths:

- 1** Develop informational sessions, trainings, or webinars that are targeted to various stages of company development. Topics might include those in this summit, information about potential policy changes in the pipeline, such as AdvaMed's proposed voluntary Coverage with Evidence Development (CED) process; how to gain access to hospital chargemasters and individual payer payment rates; and reimbursement strategies for CMS and private payers.
- 2** Create strategies to help new companies understand that reimbursement planning is as critical as regulatory planning in the development of new focused ultrasound devices.
- 3** Compile best-practices information to guide new companies, such as meeting early on with CMS, either directly or by including them in meetings with the FDA; learning about innovative FDA approval pathways like the

Breakthrough Devices program and the FDA-CMS Parallel Review Program; and hiring or consulting with reimbursement experts before embarking on clinical trials.

- 4** Introduce focused ultrasound manufacturers to industry professionals with reimbursement expertise. Develop and maintain a master list of reimbursement consultants that is sorted by specific categories.
- 5** Continue to create opportunities, like this summit, for companies to share experiences, challenges, and successes related to treatment reimbursement.
- 6** Encourage focused ultrasound manufacturers to join AdvaMed and MITA and then fully engage in the opportunities that these organizations provide, such as participation in one or more of AdvaMed's 12 Payment Working Groups.

Presentations

Jessica Foley, the Foundation’s Chief Scientific Officer, welcomed attendees to the summit. She noted that each speaker, panelist, discussion group leader, and attendee was required to read and sign the meeting’s antitrust compliance document, which outlined impermissible topics of discussion and noted implications of violating Federal antitrust laws.

The summit brought together the four focused ultrasound device companies that currently have FDA approval, with goals of discussing their reimbursement experiences, identifying challenges and barriers, and brainstorming ways to address them. The day prior, three of the companies also participated in a [Capitol Hill fly-in](#) that was organized by MITA. As part of its mission to advance the field, the Foundation seeks to identify strategies that more quickly and efficiently achieve reimbursement for focused ultrasound manufacturers and the patients they serve.

The meeting began with an overview of the Foundation’s reimbursement efforts to date. Then, Foundation partners—AdvaMed, MITA, Dobson DaVanzo & Associates, and ADVI—presented industry-specific information on several key topics of reimbursement. The sessions covered the ways that advocacy organizations are working to help manufacturers achieve reimbursement, the various pathways to reimbursement, how charges and costs affect reimbursement, and the role and process of medical coding in reimbursement.

The summit concluded with a brainstorming session and a series of private meetings between focused ultrasound manufacturers and representatives from AdvaMed, MITA, Dobson DaVanzo & Associates, and the Foundation.

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Overview and Background Information

Jessica Foley presented slides to provide background information and describe the Foundation’s reimbursement-centered activities. The Foundation was established in 2006 with the intention of making a global impact as a catalyst to accelerate the development and adoption of focused ultrasound. One of its main objectives is identifying and helping to break down barriers for the technology, including overcoming regulatory and reimbursement barriers. Although the focused ultrasound field and the Foundation have made great progress in overcoming challenges with the FDA approval process, there is not yet the same success with CMS and reimbursement in general. The Foundation is exploring how best to support efforts to speed the advancement of reimbursement for focused ultrasound.

The development landscape for the technology shows incredible growth. Over the past 14 years, focused ultrasound has become a preferred alternative for many diseases and conditions. Globally, it is under investigation or currently being used for more than 130 indications; however, none of these are widely reimbursed and only a few have achieved reimbursement of any level. The technology has already provided more than 250,000 treatments around the world, and the rate has reached approximately 50,000 treatments per year. The applications with the highest treatment rates are uterine fibroid and prostate tissue ablation; brain treatments have now surpassed 2,000 worldwide, and cancer applications are growing.

The reimbursement ecosystem is tremendously complex. Furthermore, the process is confusing, obscure, and often inefficient, especially for innovative medical devices like focused ultrasound. No previous model exists for similar devices that combine imaging and therapeutic technologies.

Overcoming impediments is the solution, and the Foundation has taken these beginning steps:

1. We partnered with MITA and created a focused ultrasound working group. Several companies have participated in the working group, including EDAP-TMS, Insightec, Profound Medical, and SonaCare. Along with the working group's monthly meetings, MITA has organized Capitol Hill meetings, fly-ins (February 2019 and March 2020), a public relations campaign which uses op-eds, blogs, and social media to share patient stories and identify barriers to adoption, and has written comment letters to government agencies.
2. We partnered with AdvaMed in 2019 and at least 11 focused ultrasound companies have become members. Along with offering incredible benefits, advocacy, resources, and educational opportunities, AdvaMed also cohosted this summit. All focused ultrasound companies should consider AdvaMed membership.
3. Beginning in 2018, we sponsored a [CMS Outpatient Prospective Payment System \(OPPS\) Reimbursement Education Program](#). At that time, reimbursement levels were cut across the spectrum of approved indications. The Foundation consulted with Dobson DaVanzo & Associates to create an education program for outpatient treatment centers that were either offering transcranial focused ultrasound as a treatment for essential tremor or considering adding it in the future.

The goals for the summit are to educate companies on key reimbursement topics, identify their current major challenges, and explore collaborative opportunities for the group, with the aim to increase patient access to focused ultrasound treatment through more widespread coverage and reimbursement.

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AdvaMed Panel

Brian O'Connor, **Don May**, and **Patrick Brennan** from AdvaMed provided an overview of their organization and its many activities with an emphasis on two of the most pertinent initiatives: the Accel Program and the Payment Team.

AdvaMed is a trade association with the intent to advance medical technology in a way that will achieve healthier lives and healthier economies around the world. The organization acts as a common voice for its 400-plus member companies (ranging from small innovators to large manufacturers) that produce medical devices, diagnostic tests, and digital health products. With an over 80-member staff, AdvaMed supports med tech companies across North America, Europe, China, India, Japan, and Latin America. Overall, AdvaMed advocates on a global basis for the highest ethical standards, timely patient access to safe and effective products, and economic policies that reward value creation.

Members of AdvaMed receive regular policy updates and daily representation in Washington, DC; access to AdvaMed staff experts in regulatory, reimbursement, legal/compliance and global markets; networking opportunities with top industry executives and with peers facing similar challenges; interactions with government agencies, including the FDA and CMS, and with federal and state legislators; discounted registration for industry-focused events and education programs; and time and money savings when procuring services and supplies through the AdvaMed purchasing group. Importantly, AdvaMed often serves as the government affairs department to provide policy and advocacy work for small companies that do not have this as an in-house capability. AdvaMed is excited about its productive relationship with the Foundation and multiple focused ultrasound companies. It aims to help tell the story of focused ultrasound and make it understandable to all.

Accel Program

Patrick Brennan described AdvaMed's **Accel Program**, which is dedicated to the needs of smaller medical technology manufacturers. Approximately 75% of AdvaMed's member companies are considered small or midsize, and 68% of them are emerging growth entities with annual sales less than or equal to \$100 million. A program similar to Accel for diagnostic companies is called **Dx**.

AdvaMed Accel facilitates a policy environment that is conducive to capital formation and innovation; it advocates for payment and regulatory policies that are favorable to emerging companies, and provides them with educational meetings and networking opportunities. AdvaMed Dx provides similar services for in vitro and other types of diagnostic companies. To serve its members, AdvaMed seeks to provide thought leadership on coding and reimbursement issues. It also educates payers by guiding and participating in company conversations with them.

Member concerns with data privacy and stewardship inspired AdvaMed to create the **Center for Digital Health**, which promotes the essential role of digital medical technology in improving patient care and health care delivery and advocates for public policies that advance digital health. The Center for Digital Health is home to the converging medical

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and digital technology companies that are leading the digital health revolution, and its members can leverage AdvaMed’s expertise and advocacy resources on digital health as well as on the full range of global policy issues critical to the medical technology industry.

All members have access to each program and division, and that access is customized based on the member company’s focus and needs. AdvaMed offers formal sector groups along with informal gathering around specific issues, such as the opioid crisis, for key advocacy activities. Members are encouraged to share their needs and experiences and ask questions on any topic.

Payment Team

Don May introduced AdvaMed’s Payment Team and described their activities. The team leads and their expertise are as follows:

Team Lead	Expertise
Chandra Branham	Coverage, diagnostics, private payer, evidence development, comparative effectiveness
DeChane Dorsey	Coding, physician payment, outpatient hospital, ambulatory surgical centers, wound care, imaging, radiation therapy
Chien-Wei (CW) Lan	Research, dialysis, quality measurement, surveys
Richard Price	Inpatient hospital billing, affordable care organizations, bundling, durable medical equipment, prosthetics/orthotics and supplies, digital health, diabetes, research

Each of these individuals leads a team that provides support for AdvaMed’s 12 Payment Working Groups, several of which apply to the focused ultrasound industry including Payment Policy, Outpatient Prospective Payment System & Ambulatory Surgical Center, Coverage Policy and Coding, and Quality. Companies that participate in these groups discuss issues, share concerns, and develop consensus for advocacy and policy development; each participant has an equal voice. If consensus is not reached, AdvaMed does not comment on an issue.

AdvaMed conducts extensive research on payment issues, and the payment groups achieved numerous successes in 2019. AdvaMed team members have had many conversations with CMS on issues such as breakthrough products. Its Payment Team identified the following value and reimbursement priorities for 2020:

- Improve coverage for breakthrough technologies.
- Advocate for improved med tech provisions in anti-kickback statute safe harbor reforms.
- Advocate for improved coverage and reimbursement of digital and diabetes technologies.

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- Track new local coverage determinations and coding processes.
- Improve coverage through a voluntary CED process.
- Engage with private payers.

AdvaMed’s [Value Initiative](#) web pages contain a variety of resources, including framework and use case publications, toolkits, and quizzes for identifying evidence and value. Framework documents include “[A Framework for Comprehensive Assessment of Medical Technologies – Defining Value in the New Health Care Ecosystem](#)” and “[A Framework for Comprehensive Assessment of the Value of Diagnostic Tests](#).” The framework for assessing medtech value accounts for all stakeholders, value drivers, patient populations, evidentiary support, timeframes, and expected impacts. It shows how value must be supported by evidence and provides eight examples of the types of evidence that can be used to achieve reimbursement (e.g., prospective cohort study, patient registries, case studies, and more).

Discussion

During the discussion, participants expressed interest in learning more about AdvaMed’s proposed [voluntary CED process](#). The group discussed value impact versus cost impact and the importance of providing equal or better clinical value at a reduced cost. It was noted that patient engagement and patient input could be leveraged for reimbursement as a new value paradigm. The group also discussed how when a new technology is adopted, an old technology fades away, which creates an economic impact across a medical specialty. There are several organizations and consultants that can help evaluate a value proposition.

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MITA

MITA is the collective voice of medical imaging equipment, radiopharmaceutical manufacturers, innovators, and product developers. MITA’s member organizations represent more than 90% of the global sales market for medical imaging technology. Its mission is to ensure patient access to innovative medical imaging technologies, reduce regulatory barriers, establish standards, and advocate for the medical imaging industry.

[Holly Grosholz](#) described how MITA collaborates with the Foundation and its member organizations to assist in the area of reimbursement. The Foundation partnered with MITA in April 2018 to raise awareness of focused ultrasound technology among policymakers, payers, and medical specialty societies. MITA’s Focused Ultrasound Section holds regular calls to discuss and align industry interests. The organization has hosted an annual Focused Ultrasound Fly-in to Capitol Hill for the past two years, and it regularly comments on regulatory legislation, engages with lawmakers on behalf of the focused ultrasound community, and creates public relations materials—such as blog posts, op-eds, and social media posts.

MITA’s Reimbursement Committee oversees federal payment policy issues relating to medical imaging. The goals of this committee are to protect reimbursement and patient access by writing comment letters in response to rule making, drafting policy statements, and developing payment policies that enhance market access to imaging services. MITA’s Technical and

Regulatory Committee oversees regulatory activity, interfaces with the FDA, and develops comment letters and long-term strategy for regulatory work and policy development within MITA. Its goals are to streamline and improve the regulatory process for bringing medical imaging devices to the market using a transparent, predictable, and timely process.⁽¹⁾

MITA is a small, agile organization that is able to create personal advocacy on Capitol Hill for expedited approval and coverage of innovative technologies. It knows how to build support for its members to ensure appropriate payment levels and how to support efficient market access for safe and effective medical imaging technologies.

Discussion

With regard to MITA's cross-sectional committees [e.g., ultrasound, MRI, X-ray, computed tomography (CT), and positron emission tomography (PET)], attendees suggested creating a focused ultrasound plus radiotherapy section. MITA and AdvaMed work together on issues of mutual interest and often advocate together, as they did on the excise tax issue. Both organizations are concerned with access to technology, and together they support the work of state associations to broaden the voice and messaging of the coalition, combine efforts on policy development to ensure that comment letters are in alignment, and hold joint events, such as insurance coverage sessions.

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Innovative FDA Programs

When the speaker from the FDA could not attend the summit due to novel coronavirus restrictions, **Chandra Branham** and **Ruey Dempsey** from AdvaMed stepped in at short notice to present information on two of the FDA's innovative programs. Together, they presented overviews of the Breakthrough Devices Program and the Payor Communications Task Force, which includes FDA-CMS Parallel Review.

Breakthrough Devices Program

The FDA's voluntary **Breakthrough Devices Program** was designed to expedite approval of innovative medical devices or device-led combination products that provide effective treatment for serious diseases and conditions. Its goal is to preserve standards while speeding the development, assessment, and review of innovative medical devices, allowing them to more quickly reach the patients and health care providers that need them. The program is not a substitute for premarket approval (PMA), 510(k) clearance, or De Novo marketing authorization pathways; rather, it works alongside them. A medical device manufacturer can apply for Breakthrough Device designation if the device provides more effective treatment or diagnosis of life-threatening conditions or non-reversible conditions and is one of the following: 1) a breakthrough technology, 2) novel, with no existing approved or cleared alternatives, 3) a significant advantage over existing alternatives, or 4) in the best interest of patients. At least 200 devices have already earned this designation, so it may not necessarily be a faster pathway. The FDA states that devices with breakthrough designation receive prioritized review on future regulatory submissions, Q-Submissions, Investigational Device Exemption (IDE) applications, and marketing submissions.

Payor Communication Task Force

With the goal of shortening the time between obtaining both FDA approval and a positive coverage decision from payers (such as CMS, private health plans, and others), the FDA's Center for Devices and Radiological Health (CDRH) established the [Payor Communication Task Force](#). The idea is that early communication between device manufacturers and payers leads manufacturers to design clinical trials that produce two kinds of data: those required for regulatory approval or clearance (usually safety and efficacy data) and those required for positive coverage determinations (usually comparative data for improved health outcomes, reduced cost, or both). Delays in coverage, payment, and use decisions ultimately delay patient access to medical devices, so this program works to bring payers to the table earlier in the process. CDRH acts as an intermediary, and coverage is not guaranteed, but the idea is for payers to ask for specific types of data on the front end.

Now falling under the Payor Communication Task Force, the FDA-CMS Parallel Review program was designed to facilitate parallel review with CMS. The FDA-CMS Parallel Review began as a pilot program in 2011, to establish a mechanism between the FDA and CMS for simultaneously reviewing clinical data. In October 2016, the FDA and CMS fully implemented the program and extended it indefinitely. Parallel Review's two stages are meeting with the manufacturer to provide initial feedback on their proposed pivotal clinical trial for FDA approval, and then concurrently but independently reviewing the device's clinical trial results. Critics note that only two diagnostic companies have successfully benefitted from Parallel Review from start to finish.⁽²⁾⁽³⁾

Discussion

Participants asked whether there was a risk for a negative outcome with the FDA's Breakthrough Devices program. The invited experts said that the only risks come from the accompanying regulatory pathway itself [e.g., PMA, 510(k) clearance, or DeNovo marketing authorization]. When asked whether a device that was originally approved through the PMA pathway could later qualify for the Breakthrough Devices program if it applied for approval for a novel indication, the invited experts responded that it could if the device had changed. This also applies when an approved device has not changed but is pursuing a new indication if the new indication is a breakthrough—for instance, if no other devices treated that condition.

When completing the application for Breakthrough Device designation, participants asked how a company could demonstrate effectiveness prior to completing a clinical trial. This led to a brief discussion of what constitutes meaningful data, such as preclinical work and animal studies. The FDA offers presubmission “Q” meetings where they comment on the types of additional data that they would like, and payers are allowed to come to these meetings. A device cannot receive breakthrough designation after achieving regulatory approval, which also removes the possibility of receiving the potential early reimbursement benefit. AdvaMed offers their members a series of regulatory best practices on their website.

The invited experts maintained that applying for breakthrough device designation was not burdensome for companies, but the designation required additional up-front work and FDA meetings that necessitated appropriate planning. The FDA must provide a decision in 30 days. It is best to apply before starting down another pathway, but it is never too late. It is worth asking the FDA for feedback.

Discussion turned to United States Senate Bill 2326, the [New Opportunities for Value that Extends Lives \(NOVEL\) Act of 2019](#), which was introduced in the Senate on July 30, 2019. It proposes provisional CMS coverage for breakthrough devices. Foundation staff members want companies to know about Breakthrough Device designation, because having it might help a device achieve coverage sooner if the NOVEL Act or similar legislation becomes law. The primary issue with achieving coverage is obtaining post-market, long-term data—the evidence that payers require unless a device fulfills an unmet need.

Companies pursuing 510(k) clearance do not typically collect reimbursement or coverage evidence. AdvaMed staff encouraged companies to engage the FDA Payor Communications Task Force because it is important to talk to payers early and ask what is needed for reimbursement. Payers typically want to see the reasonable and necessary characteristics of a product. Knowing what evidence payers require can influence strategic decisions and shorten the gap as a company moves toward entering the market.

The group questioned and discussed specific details about the FDA-CMS Parallel Review Program, including cost criteria, differences between inpatient and outpatient procedures, and the definition of “significant clinical improvement.” Any breakthrough device with a means to cost criteria should also meet the criteria for substantial clinical improvement. A bill has been proposed for improved CMS reimbursement: “Ensuring Patient Access to Critical Breakthrough Products Act of 2019,” was introduced on December 6, 2019. AdvaMed is lobbying on behalf of this bill.^(4,5) Despite AdvaMed’s efforts in this area, Breakthrough Device designation does not guarantee that payers will make a determination that it is reasonable and necessary.

Although AdvaMed did not present specific information on this program, attendees asked questions about the CMS New Technology Add-on Payments (NTAP) program. The discussion included whether the program was specific to implantable devices and how long a device had to remain in the body, whether transrectal high-intensity focused ultrasound (HIFU) probes qualified, the difference between inpatient and outpatient procedures, the single-patient use component, and how CMS calculated the level of the add-on payment. The group asked for additional information and guidance on this program along with a list of consultants who have successfully worked on this program.

Participants raised the issue of drug-device combination pathways for focused ultrasound—induced drug delivery. The invited experts said that combination products with a drug-based mode of action are often regulated by FDA’s Center for Drug Evaluation and Research (CDER). However, the FDA’s Office of Combination Products decides this on a case-by-case basis, and there is not yet a clear pathway established for drug/device combinations in the focused ultrasound space.

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Charges, Costs, and Their Impact on Reimbursement Levels

Allen Dobson and **Steven Heath** presented an overview of how hospital charges and costs ultimately impact future reimbursement levels. Their company, Dobson DaVanzo & Associates, is a health economics and policy consulting firm based in Washington, DC. Their work influences the design of financial demonstrations and public policy decisions, appears in legislation and regulation, and has helped courts, plaintiffs, and defendants understand the economic value of various health care issues.

Understanding hospital accounting is important for the focused ultrasound industry because many procedures involve Medicare payments in the outpatient hospital setting. Importantly, each hospital's decisions about charges and which revenue centers to use impact future payment rates for a given procedure or group of procedures. The language of hospital pricing and reimbursement includes several key terms, which are outlined in the "Glossary of Key Terms" found at the end of this white paper.

How are hospitals reimbursed for outpatient care? The OPSS sets payment levels for individual services, which are identified with Healthcare Common Procedure Coding System (HCPCS) codes using a set of relative weights, a conversion factor, and adjustments for geographic differences in input prices. Hospitals can also receive additional payments in the form of outlier adjustments for extraordinarily high-cost services and pass-through payments for some new technologies. OPSS payments are grouped into Ambulatory Payment Classifications (APCs). APCs are made up of individual services that are grouped based on resource utilization and clinical similarity. All services within an APC have the same payment rate, hence there can be winners and losers within a single APC.(6)

New technologies can be paid for in the outpatient setting, but there is a waiting period for data collection. CMS assigns some new services "new technology" APCs based only on similarity of resource use. They establish new technology APCs because some services are too new to be represented in the claims data that the agency uses to develop initial payment rates for OPSS. Services remain in these APCs for two to three years while CMS collects the data necessary to develop payment rates for them. Each year, CMS determines which new services, if any, should be placed in new technology APCs. Payments for new technology APCs are not subject to budget neutrality adjustments, so they increase total OPSS spending.(6)

Hospitals develop charges based on their chargemasters. A chargemaster is a lengthy list of hospital prices for each service or item that a hospital offers to a patient or insurer. The amount paid by patients and insurers is typically heavily discounted from the amount shown on the chargemaster. The average hospital has 11,000 chargemaster lines, but 30,000 lines are possible from 50 to 70 different departments. Uwe Reinhardt, a renowned health economist, states that there is "incomprehensible variation" in chargemaster prices across hospitals within a state.(7) There is no set practice or rule for updating chargemaster list prices. Hospitals may update them annually or more often, and different items may be updated by different percentages. Hospitals need to update their charges to reflect new technology and to remain competitive with other hospitals, but they are not allowed to set

different charges for different payers. Beginning in 2021, new transparency rules from CMS will force hospitals to make their chargemasters publicly available in some form (8), although nearly every hospital has made this information available since late 2019. In addition, hospitals will soon need to make available to the public the payment rate they receive from individual payers.(9)

There are multiple challenges with the way that hospitals determine charges. For example, hospitals often set charges—based on their actual costs of performing a procedure—for uncovered services at a rate that makes cash payment affordable. But when this “affordable” procedure gets approved for Medicare coverage, the cost is stepped down by Medicare’s Cost to Charge Ratio (CCR), so the cost that CMS sees is no longer the actual cost, and in certain instances, this inaccurate cost is what CMS uses to set future APC payment rates. This creates a situation where a small number of claims with a low charge and/or a low CCR can have a disproportionately large impact on CMS calculations and, thus, payments. Within the hospital, many different departments and staff touch the charge setting process such that often no coherent strategy emerges. Unwinding an entry on the chargemaster can be extremely difficult.

There are several important issues for hospitals to consider when determining charges for focused ultrasound treatments. The set charges will determine future APC payment rates, so it is important that Medicare OPPS payments are aligned with the actual production costs for focused ultrasound. Setting charges too low now may erode future reimbursement levels. If this occurs, facilities will lose money with every focused ultrasound treatment performed, physicians will be denied the opportunity to use the technology, and patients will be refused access to focused ultrasound procedures on financial grounds.

OPPS determines hospital payments for outpatient services using costs, as calculated annually from Medicare claims and the hospital’s Medicare Cost Report (MCR). Medicare claims contain the facility charge for each item billed during an outpatient visit. This charge is attached to a revenue center on the claim. Revenue centers crosswalk to cost centers using a Medicare-provided table. Each MCR cost center has an associated CCR assigned by CMS, based on historical data. Revenue center charges are multiplied by the relevant cost center’s CCR to produce “costs.” The CCR for a specific cost center varies from facility to facility.

In the near term, the impact of charges and CCRs on payments can be deceiving. If the hospital sets the procedure cost at \$50,000 and it is multiplied by a CCR of 0.15, the payment is \$7,500. But what if the true cost to the facility for performing the procedure is about \$20,000? Then billing through the cost center with a CCR of 0.40 is the only way to not lose money on this procedure. This is why different hospitals use different revenue centers, and this is what leads to the incredible variability in CCRs. Hospitals do not want to switch a procedure to a cost center with a lower CCR, and the average CCR varies by revenue center. For focused ultrasound, most hospitals are using one of three revenue centers, and these three CCRs vary from 0.127 to 0.450:

- 402: Other imaging services: ultrasound. The average CCR among 33% of providers is 0.198.

- 610: Magnetic resonance technology (MRT). The average CCR among 12% of providers is 0.127.
- 761: Treatment/observation room. The average CCR among 30% of providers is 0.450.

Over the long term, charges and CCR levels continue to impact payment levels. APCs define the maximum Medicare payment level for groups of procedures that are clinically similar, and Medicare annually reassesses APC levels for all treatment codes. During this reassessment, CMS averages claims cost values that were submitted over a one-year period from two years back. If the average assigned cost for any one procedural code is substantially below its designated APC payment level, it can be reassigned to an APC level with a lower reimbursement amount. For a new technology like focused ultrasound, the volume of available claims can be very small (e.g., less than 100 procedures is a low claim volume). Even just a few claims that are not reflective of actual costs can have a large negative impact on future CMS reimbursement. With inaccurate costing, the APC level eventually falls below the actual cost of performing the procedure, which is financially untenable for treatment centers. Facilities will eventually deny physicians the ability to perform the service.

Determining facility charges for focused ultrasound procedures is a critical part of the reimbursement process, because what one facility charges for a procedure impacts future payments for all treatment facilities. If submitted charges at any one facility are too low, or if the revenue center to which the charges are assigned has a CCR that is too low, the resulting low-cost estimates drag down the Medicare reimbursement rate for all other treating facilities. The “average” CMS cost estimate will be too low relative to actual costs incurred. When hospitals are not adequately reimbursed for the costs associated with a treatment, the shortfall impedes the technology’s long-term viability. This pricing mistake has a long-term impact on the facility, its attending physicians, and ultimately on the patients that they both serve.

Manufacturers can ask hospitals (or hospitals can ask themselves) several questions when determining charges for focused ultrasound procedures:

1. How do the charges in your chargemaster translate to allowable Medicare costs and/or billings? Some facilities use a heuristic, such as “2- to 3-times the APC level” when they set charges, but this is not ideal because CMS is rigorous in their practice of “cost = charge x CCR.”
2. How do APC payments compare to the actual cost to the facility of performing the procedure? Do you know the true cost of performing the focused ultrasound procedure? Are you potentially losing money with every focused ultrasound procedure performed?
3. How do these allowable costs compare with the current APC payment level for that procedure? Am I putting the field of focused ultrasound at risk, possibly denying future patients access to this technology?

Discussion

The invited experts said that hospitals are trying to set prices for new technologies by comparing them to old procedures, but this approach confounds the situation. They added that when hospitals try to set an affordable “out-of-pocket” price, it creates an unintended, counter-intuitive problem down the road when Medicare applies its CCR.

Participants said that hospitals were concerned with how pricing impacted other procedures. To help hospitals understand the impact of their data, Dobson DaVanzo staff members show facilities their data as it appears in Medicare reports. These reports can be helpful to document unfair charges, demonstrate how they pull the APC payment rate down, and illustrate the implications of each pricing decision. Many facilities are afraid to question Medicare processes, so it takes a lot of courage to get them to change. It’s a slow process of education followed by an “aha” moment. CMS encourages companies to educate hospitals without giving them any numbers, because charges for the same procedure vary widely. Claims data are available for specific facilities.

When participants asked whether geometric mean costs were determined multiple times, Dobson DaVanzo staff said that they represent the aggregate of all costs that are allowed. They added that the geometric mean is only applied once, at the end of the reimbursement equation. A participant said that to get paid the correct amount, the hospital that is the largest user of one focused ultrasound device bills both the APC and an unlisted code and then splits the cost between the two. He asked whether those claims would be used to set future payment levels. Dobson DaVanzo staff agreed that this was a timely question and offered to find the information and recalculate the geometric mean.

Participants raised the topic of hospital equipment rental fees, noting that there is a rental code (i.e., 291). Dobson DaVanzo staff said that some hospitals amortize costs, and this led to a discussion of capital equipment cost levels for various hospital departments. Reverse engineering the Medicare fee schedule gave Dobson DaVanzo an idea of how Medicare would benchmark capital equipment costs. A participant noted that the procedure costs that hospitals are calculating are fairly accurate, but the system is flawed if the urology APC for prostate treatment is \$10,000. Invited experts said that the new transparency laws should help reform the system and bring more rational thought on this topic.

Because hospitals that are careless about pricing can negatively affect the overall geometric mean, and therefore negatively affect a company’s future ability to sell their devices, companies wondered whether reviewing Medicare claims data could help them determine which hospitals they should target in selling their technology. When a participant asked whether companies could analyze the impact of current pricing levels without waiting two years, the invited experts affirmed that the levels could be simulated. Other questions arose about refiling errant claims and the possibility of a Medicare audit. Invited experts noted that hospitals will not take any risk that might jeopardize their Medicare status.

Dobson DaVanzo’s consulting work was a topic of interest, including whether the Foundation could provide assistance in this area. The Foundation stated that the essential tremor project was a beta test to see if the education process would work. Preliminary

evidence suggested that it does. Scaling this to all sites for all manufacturers would be cost prohibitive; however, the Foundation suggested discussing whether some type of collaborative effort might work for all companies. Attendees agreed that this work done early in the reimbursement process could help secure the future of new focused ultrasound applications.

The final part of the discussion centered on brainstorming ways to better communicate with hospitals, hospital CEOs, and the AHA as a whole. An invited expert shared a story about a time when CMS changed imaging tests from overall cost centers to center-specific cost centers. AdvaMed tried to work with the AHA on this issue, and CMS delayed the change three years to avoid hurting imaging services. But it was still a major struggle to get hospitals to listen, even with the support of the AHA. A participant said that hospital communication issues have existed for decades, because other new technologies have had the same issues. The problem has not improved over time. Hospitals tend to focus on one problem at a time rather than taking a system-wide approach; they do not have a holistic or long-term point of view. Hospital CEOs do not typically engage unless they feel threatened, and it is difficult to develop relationships with constant turnover in administrations. One potential idea was to have an increased presence at hospital CEO and administrator conferences, to make presentations and share the costs of developing new technology.

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Coding Overview

Michael Beebe, a partner at ADVI, has offered consulting services for more than 11 years on medical coding. In his presentation, he described how reimbursement codes are being used in the field of focused ultrasound, identified coding challenges, and suggested possible solutions.

Medical coding is a precursor to medical billing. The health care industry uses numeric or alphanumeric codes to describe diseases, conditions, and the procedures to treat them. The American Medical Association (AMA) plays a major role in developing and maintaining reimbursement codes. Along with other existing coding mechanisms, the AMA's Current Procedural Terminology (CPT®) coding system is used to ensure that physicians receive accurate payment and to collect and analyze a wide variety of patient care data. Published, owned, and copyrighted by the AMA, CPT® codes cover a wide variety of physician-provided services and are the primary way that medical services are reported in the US. There are three types of five-character CPT® codes:

- Category 1 codes describe general services and procedures performed by providers.
- Category 2 codes track follow up and outcomes.
- Category 3 codes indicate the use of an emerging technology.

Importantly, two-character modifiers can be added to CPT® codes to explain changes to a procedure.

These codes are updated and published annually by the CPT® Editorial Panel. When a new procedure is developed, new CPT® codes must be created. Anyone can apply for a new code, and applications are due 12 weeks ahead of each Editorial Panel meeting. These meetings, which are held three times each year in February, May, and October, are open to advisors, staff, stakeholders, and the public, but panel votes are secret to maintain the confidentiality of panel decisions. The agenda for each meeting is posted in advance to allow time for interested parties to comment. The outcome of each meeting is posted approximately one month later.

The AMA has a Relative Value Scale (RVS) Update Committee (RUC), which is a volunteer group of 31 multispecialty physicians who are tasked with advising CMS on the resources required to provide physician services. This group, which is actually run by specialty societies, makes a recommendation to CMS on behalf of the AMA on the number of Relative Value Units (RVUs) for each procedure. RUC meetings are closed to all except RUC members, alternates, advisors, staff, and consultants. Industry representatives are excluded, no agenda is posted, and no information is made public about the meetings. CMS takes RUC recommendations into account when determining Medicare payment levels, but the recommendations to CMS are confidential.

CPT® codes and RUC recommendations significantly impact reimbursement for focused ultrasound procedures. Because of the timing of Editorial Panel and RUC meetings, new CPT® codes are not published or reimbursed by CMS for at least 14 to 15 months after they are reviewed and approved. The Medicare Physician Fee Schedule takes longer than the CPT® process. Missing a meeting deadline could delay reimbursement by 30 months. CPT® codes are granted based on the submission of required evidence and required utilization. Evidence requirements include published data from comparative studies conducted in non-overlapping patient populations that are written by different authors. Evidence can come from cohort studies or case-control studies, but it must also meet specialty society requirements. Utilization requirements must show that a procedure or service is conducted at a frequency that is consistent with the intended clinical use; that is, a service for a common condition should have high volume, whereas a service commonly performed for a rare condition may have low volume. Procedures should be performed by many physicians or other qualified health care professionals across the US. This creates a “catch-22” issue for new technology, because obtaining a CPT® code requires utilization but physicians are reluctant to use new devices without payment, which requires a CPT® code. It is unreasonable to ask a physician or a hospital to take a loss to provide a new technology to patients. Reimbursement should not be tied to CPT® codes.

Specialty society support is not required to obtain a CPT® Category I code, but the Editorial Panel is unlikely to grant a Category I code without specialty society support. The Editorial Panel views specialties as representing practicing physicians who would provide a service or procedure to patients, but specialties have their own interests—namely, to maintain their scope of practice and protect the pricing of existing procedures. Specialty physicians are often more interested in RUC resurveys, so they have no bandwidth for new technologies. Many specialty societies do not want to work with industry, because they see it as a conflict of interest.

Focused Ultrasound Foundation

The following CPT® codes have been assigned or proposed for focused ultrasound procedures:

- 5XXXX Ablation of prostate tissue, transrectal, HIFU, with ultrasound guidance
- 0071T Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue
- 0072T Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue
- 0398T Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed

Coding Challenges

The Editorial Panel can issue a CPT® Category III (emerging technology) code against the desire of an applicant. Category III codes are problematic after FDA approval, because companies must conduct new studies to convert a Category III code into a Category I code. Despite the vast amount of knowledge that industry representatives have about new technologies, RUC meetings are closed to the public, and the process is aggressively biased against industry. Industry representatives can be blamed for bringing code requests forward too early. Several technologies have had to be contractor priced due to a lack of knowledge among RUC members. Despite being excluded from meetings, device companies are allowed to contribute paid invoices for supplies and equipment, and they are sometimes able to submit input from a focused sample of physician users.

To further complicate matters, when a new CPT® code is added or revised, the AMA requires the Editorial Board to resurvey that family of codes. A Resurvey and Relativity Assessment Workgroup (RAW) reviews statistics and revalues existing codes. This process places existing codes at risk of receiving a lower value, and so specialty societies will not support codes for new technologies that place existing codes in danger of being revalued (i.e., devalued). This process of defending and resurveying codes keeps specialty societies occupied, and they are more concerned with losing their current sources of revenue than with adding potential new sources.

Possible Coding Solutions

To prevent issues with applying for and receiving a CPT® code, a device company must:

- Plan many months or years ahead of FDA approval
- Work with specialty societies to discuss evidence requirements, code family resurvey concerns, and the costs associated with implementing the technology

- Develop a physician training program
- Consider obtaining a category III CPT® code while pursuing FDA approval
- Develop coding and coverage evidence, beyond the evidence required by the FDA

To create systematic change, the focused ultrasound industry could consider advocating for the following reforms

- Allowing companies to request an unlisted code instead of having a Category III code forced on them
- Demonstrating that surveying a minimum of 30 physicians should be adequate to show utilization
- Developing a process to expedite new technology so that it is not required to wait up to 15 months for coding revisions; the RUC already identifies new technologies; CPT® applicants should be able to withdraw an application and use it for budget neutrality
- Designating a member of the CPT® Editorial Panel to represent the interests of industry because payers and providers are represented, but device manufacturers are not
- Supporting the idea that new technologies, as identified by the RUC, should not subject code families to resurvey until the standard 3-year review period has been achieved

Discussion

When a participant asked whether CPT® codes could be deleted, an invited expert said that a company can request that a code be deleted but the Editorial Panel generally favors keeping them. The group briefly discussed the lack of incentive for medical innovation in this setting, especially when specialty societies are unwilling to support innovation that places risk on revaluing existing codes.

Asked how long it takes for the results of a RUC meeting to become publicly available, the invited expert said that it usually takes a month to 6 weeks, but the results are not released to industry. For example, a company presenting a code in October 2019 for the 2021 fee schedule will find out when the proposed rule comes out in the first week of July. RUC meeting summaries are not published until after CMS publishes its final rulings. A participant asked whether there were any avenues for RUC to reconsider that a physician payment level was unsatisfactory. An invited expert replied that the physician payment side was limited, and that CMS liked to have specialty competition. Companies sometimes gather data on technical considerations, physician time, code comparisons, and practice expenses, but it is a fight and there is not much time to respond to a proposed rule.

Responding to a question about contractor status codes (C-codes), an invited expert explained that CMS assigns C-codes for hospital outpatient procedures. C-codes are unique temporary pricing codes that are only valid for Medicare claims for hospital outpatient department services and procedures. CMS does not establish fees for C-codes; they are priced per contractor discretion. Each year these code prices are reviewed and revised, and the price increase and/or decrease varies from code to code. Prices are not normally determined until they are billed.

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Final Discussion

Participants offered the following thoughts during the final discussion:

- It is unclear whether the NOVEL Act of 2019, which was introduced on July 30, 2019, would benefit the entire focused ultrasound industry or primarily just the early stage companies. The NOVEL act specifies that the technology must be deemed “breakthrough” by the FDA.
- AdvaMed’s proposed [voluntary CED approach](#) might be promising for Category III reimbursement. It is a new approach that has been developed for any technology that does not have coverage but is not designated breakthrough. It provides a mechanism for a company with an approved technology to gather evidence for a better reimbursement code, but this approach would not help a company that was unsatisfied with its current payment level.
- In France, the “Forfait Innovation” program selected focused ultrasound as one of the first technologies for allowing coverage at a limited number of centers while comparative data are collected. The procedures are reimbursed at the same rate as surgery. Centers must log all cases and compare effectiveness and cost data.
- Reimbursement outcomes differ for established, older companies versus those trying to enter the market. Each has different needs and purposes. The Foundation has relationships with both types of companies and is in a unique position to support companies with future potential and those further along. AdvaMed also supports all companies in different stages of development.
- The IDE regulatory pathway, such as that followed by [Profound Medical](#), created coverage issues (e.g., CMS did not know what to do.). Payer processes have not evolved along with regulatory processes. When new evidence and new trials are needed to receive coverage, when is enough enough?
- Many companies that work hard to receive FDA approval do not realize that they should also consider reimbursement during those early stages

of product development. If not pursued simultaneously, reimbursement is not achievable until 5 or 6 years later. Procedure codes are also assigned long after FDA approval. Some companies wondered whether achieving reimbursement was truly the end, or did the target move once again?

- After completing regulatory approval, securing a procedure code, and achieving reimbursement, another device company target is garnering specialty medical society support. This is a point of influence that must be recognized. Physician society support along the entire way is critical. Some societies, such as the American Urological Association (AUA) have a guideline group that is separate from the coding group. Talking to both groups is important because either, or both, may choose to offer support toward reimbursement efforts. It is more than challenging to garner support from groups such as the AUA. Inclusion into specialty society guidelines can take 5 to 10 years. A positive position statement is helpful.
- Focused ultrasound treatment of painful bone metastases is covered under an outpatient hospital code from the HCPCS. The AMA assigns CPT® codes. CPT® category “99” codes are reimbursed as provider services and ambulatory service center modifiers.
- Focused ultrasound treatment of uterine fibroids has failed to achieve reimbursement. Any centers that still offer it use a cash payment system that is based on an amount that patients are willing to pay. By the time a patient reaches the age to qualify for Medicare, she usually is no longer suffering from uterine fibroids, so CMS coverage is unlikely.

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Breakout Sessions

The summit concluded with a series of private meetings between focused ultrasound manufacturers and representatives from AdvaMed, MITA, Dobson DaVanzo & Associates, and the Foundation. Each breakout session lasted approximately 30 minutes. These small group meetings allowed company representatives to have in-depth conversations on the topics that were most pertinent to each of them.

A Roadmap Forward

To move forward in assisting focused ultrasound manufacturers with understanding reimbursement and navigating its many complex components, participants recommended that the Foundation take the following steps, in collaboration with partners AdvaMed and MITA.

- 1** Develop informational sessions, trainings, and webinars that are targeted to various stages of company development. Topics might include those in this summit and information about potential policy changes in the pipeline, such as AdvaMed's proposed voluntary CED process; how to gain access to hospital chargemasters and individual payer payment rates; and reimbursement strategies for CMS and private payers.
- 2** Create strategies to help new companies understand that reimbursement planning is as critical as regulatory planning in the development of new focused ultrasound devices.
- 3** Compile best-practices information to guide new companies, such as meeting early on with CMS, either directly or by including them in meetings with the FDA; learning about innovative FDA approval pathways like the Breakthrough Devices program and the FDA-CMS Parallel Review program; and hiring or consulting with reimbursement experts before embarking on clinical trials.
- 4** Introduce focused ultrasound manufacturers to industry professionals with reimbursement expertise. Develop and maintain a master list of reimbursement consultants that is sorted by specific categories.
- 5** Continue to create opportunities, like this summit, for companies to share experiences, challenges, and successes related to treatment reimbursement.
- 6** Encourage focused ultrasound manufacturers to join AdvaMed and MITA and then fully engage in the opportunities that these organizations provide, such as participation in one or more of AdvaMed's 12 Payment Working Groups.

Abbreviations

AdvaMed	Advanced Medical Technology Association
AMA	American Medical Association
APC	Ambulatory Payment Classification
AUA	American Urological Association
C-codes	Contractor status codes
CCR	Cost-to-Charge Ratio
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CED	Coverage with Evidence Development
CMS	Centers for Medicare & Medicaid Services
CPT®	Current Procedural Terminology
FDA	United States Food & Drug Administration
HCPCS	Healthcare Common Procedure Coding System
HIFU	High-intensity focused ultrasound
IDE	Investigational Device Exemption
MCR	Medicare Cost Report
MITA	Medical Imaging & Technology Alliance
MRgFUS	Magnetic Resonance—guided Focused Ultrasound
MRI	Magnetic Resonance Imaging
MRT	Magnetic Resonance Technology
NOVEL	New Opportunities for Value that Extends Lives Act
NTAPs	New Technology Add-on Payments
OPPS	Outpatient Prospective Payment System
PMA	Premarket Approval
RAW	Relativity Assessment Workgroup
RUC	RVS Update Committee
RVS	Relative Value Scale
RVU	Relative Value Unit

Glossary

Ambulatory Payment Classification (APC)

Medicare's statistical system for classifying any outpatient procedure according to its clinical and similar cost structures. For the purposes of payment policy, cost and charges are calculated by APC.

Chargemaster

A lengthy list of hospital prices for each service or item that a hospital offers to a patient or an insurer.

Cost-to-Charge Ratio (CCR)

Department-level costs from Medicare Cost Report cost centers/charges from revenue centers from claims where cost centers are crosswalked to revenue centers.

FUS Partners

The Focused Ultrasound Foundation's program to foster relationships among community members seeking assistance with financing, partnerships, technology transfer, and academic research opportunities.

Geometric Mean

A median value that serves as the basis of CMS' OPSS payments. It is determined by calculating the mean of the logs of all the values under consideration, then calculating the antilog.

Healthcare Common Procedure Coding System (HCPCS)

Often pronounced by its acronym as "hick picks," these are the health care procedure codes used by Medicare. They are based on the AMA's CPT® codes.

Healthcare Provider Cost Reporting Information System (HCRIS)

The system that collects data from Medicare Cost Reports. Cost report files are all available for download from the following website: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/>.

Medicare Cost Report (MCR) Worksheet

A section within the Medicare Cost Report that collects specific financial or utilization data from an institution that bills Medicare patients, such as an acute-care hospital.

New Technology Add-on Payments (NTAPs)

When newness, cost, and clinical improvement criteria are met, CMS may provide additional payment for new, high-cost technologies in the inpatient setting. An NTAP provides additional payment to hospitals above the standard payment amount, but NTAP designation lasts no more than 3 years for a specific indication.

Outpatient Prospective Payment System (OPPS)

A system that classifies all hospital outpatient services into Ambulatory Payment Classifications (APCs). A hospital may, depending on a variety of factors, be paid for more than one APC or for more than one occurrence of the same APC at any given encounter.

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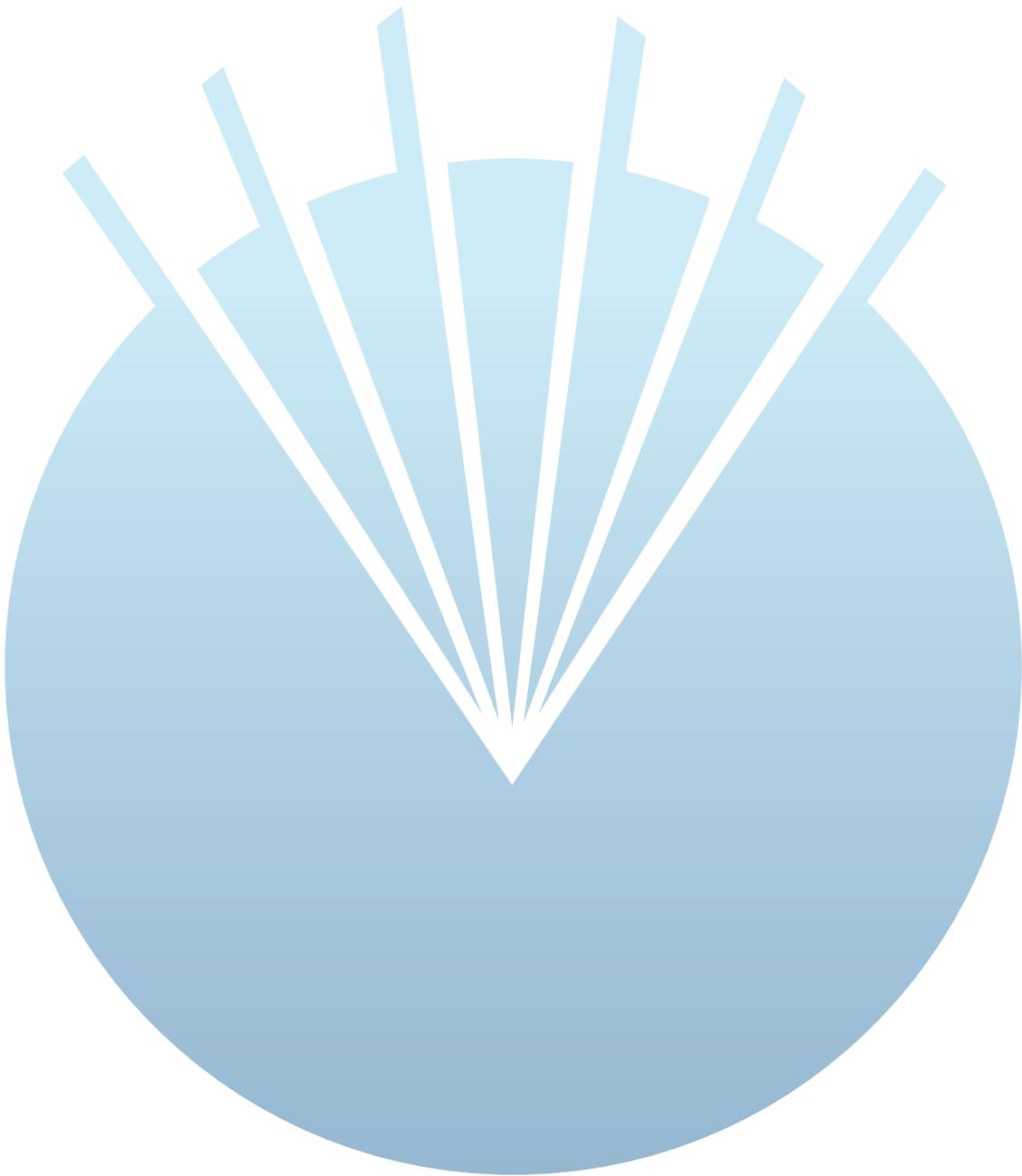
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