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Discern Health is a consulting firm that works with clients across the private and public sectors to improve health and health care. Our focus is enhancing the value of health care services through quality-based payment and delivery models. These models align performance with incentives by rewarding doctors, hospitals, suppliers, and patients for working together to improve health outcomes and health care processes, while lowering total costs. Discern has been involved in value-based purchasing projects since its founding in 2004. Discern's clients include a range of organizations—pharmaceutical companies, providers, payers, policymakers, purchasers, and national thought leadership organizations—that are driving the agenda for change in health care. More information on Discern is available at www.discernhealth.com.

The Advanced Medical Technology Association (AdvaMed) is a trade association that leads the effort to advance medical technology in order to achieve healthier lives and healthier economies around the world. 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. AdvaMed’s member companies range from the largest to the smallest medical technology innovators and companies. The Association acts as the common voice for companies producing medical devices, diagnostic products and health information systems. More information on AdvaMed is available at www.advamed.org.
EXECUTIVE SUMMARY

This white paper explores the impact of quality measure gaps for conditions and procedures treated through innovative medical technology. The paper identifies opportunities to fill critical gaps and improve measure sets for value-based care models.

The Quality Measurement Imperative

Value-based payment (VBP) for health care is rapidly replacing volume-based fee-for-service. VBP models are designed to create financial incentives for lower-cost, higher-quality care. Financial incentives used in value-based arrangements range from enhanced fee-for-service payments that encourage better care management to episode- or population-based payments that require providers to manage costs of care and meet quality benchmarks. VBP is also intended to encourage provider coordination and integration of patient care.

Quality measures are an essential element of VBP models. Effective and meaningful measurement allows payers to reward appropriate care delivery, providers to identify areas for quality improvement, and patients and purchasers to compare providers based on quality. Because VBP models include cost containment incentives, quality measures are essential to ensure that providers do not sacrifice quality of care to achieve financial benefits or avoid financial penalties. Quality measures must also be considered in the context of model design. VBP performance is often assessed during the course of a treatment episode with a brief follow-up period or a limited performance period, usually a single calendar year. The value of innovative technologies is often realized over a longer term. Outcome measures—assessing issues such as functional status or re-operations—must be considered over a longer time horizon so that program participants are not being scored against insufficient quality targets. The risks associated with inadequate quality measures in VBP models include:

- Overuse or underuse of services, where the value of outcomes associated with costlier care is not recognized under a payment model.
- Safety issues, where less effective, but less expensive, services or therapies are selected despite safer, but more expensive, alternatives.
- Stifled innovation, where short-term financial incentives discourage adoption of more expensive new products or services that offer long-term improvements in care.

Having the measures needed to assess the value of health care is increasingly important. During an October 30, 2017 meeting of the Health Care Payment Learning and Action Network (HCP-LAN), Seema Verma, Administrator of the Centers for Medicare & Medicaid Services (CMS), announced the “Meaningful Measures” Initiative, an effort to ensure that measure sets are streamlined, outcomes-based, and meaningful to clinicians and patients. The purpose of CMS’ initiative is to reduce provider reporting burden while narrowing measure sets to focus on the most important aspects of care. CMS hopes to achieve this goal by directing measure development to high-priority areas. The Medicare Payment Advisory Commission (MedPAC) has also urged CMS to refine and enhance the measure sets for Medicare quality programs to
address the cost of measure reporting and overreliance on process measures and self-reported performance. MedPAC has been particularly critical of the measures for the Merit-Based Incentive Payment System (MIPS).²

The CMS initiative and MedPAC recommendations reinforce the need for new measures that put patients’ interests and preferences first and are seen as important by providers. Medical technology plays a significant role in the patient care continuum, from screening to diagnosis to treatment and monitoring. This report recommends measure concepts for assessing the appropriate use and demonstrating the value of medical technologies for improving patient care and outcomes.

**Medical Technology-Related Quality Measure Gaps**

Quality measures can help balance the financial incentives of VBP. Without effective and meaningful quality measures, VBP models may create risks for inappropriate care delivery. Quality measure gaps include both gaps in available measures and gaps in existing VBP measure sets where measures are available but are not being used.

Quality measures currently focus on the most prevalent and costly chronic conditions, such as cardiovascular disease and diabetes, and conditions and procedures where costs are highly variable, such as joint replacement surgery. Measures are often focused on whether care meets appropriate clinical guidelines (e.g., eye exams for patients with diabetes, falls screening for elderly patients) or whether medical therapy is initiated in a timely and appropriate way (e.g., use of aspirin or antithrombotic therapy for ischemic vascular disease).

Measure sets do not yet typically include quality measures that reflect the value of medical technology, such as the ability to provide more accurate and timely diagnoses, more effective surgical procedures with fewer complications, or faster and more comprehensive clinical data through portable or point-of-care devices. Outcomes that may be linked to optimal use of technology usually assess short-term utilization and may not accurately reflect longer-term, patient-centered measures such as changes in functional status or quality of life.

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**Figure 1. Selected Medical Technology Topics**

- **Continuous Glucose Monitoring and Sensor-Augmented Insulin Pumps for Type 1 Diabetes**
- **Diagnostic Tests to Prevent Antimicrobial Resistance for Community-Acquired Pneumonia**
- **Hip and Knee Implants for Total Hip or Knee Arthroplasty**
- **Minimally Invasive Colectomy for Inflammatory Bowel Disease**
- **Negative Pressure Wound Therapy for Chronic Wound Care**
- **Prothrombin Time INR Home Testing for Pulmonary Embolism**
- **Stereotactic Body Radiation Therapy for Non-Small Cell Lung Cancer**
- **Telehealth and Remote Patient Monitoring for Heart Failure**
Methods and Key Findings

This white paper examines measure gaps across eight diverse clinical areas and example medical technologies that are indicated for the care of those conditions, listed in Figure 1.

Discern Health, a quality measurement and VBP-focused consulting firm, used a multi-step logic model to compare available quality measures to current clinical practice recommendations. Discern Health identified measurement gaps that, if addressed, could improve quality assessments for each of the medical technology topics. Gaps include both useful measures that are available but are not used in VBP models, as well as areas where measures do not exist but for which new measure concepts could be developed.

Numerous gaps were identified for each of the eight topics in the measure sets used for Medicare VBP programs and demonstration models. To validate the findings, Discern Health conducted targeted discussions on each topic with clinical subject matter experts, including subject matter experts from medical technology organizations.

The gap analysis generated important findings:

- There are significant gaps—areas where measures are not being used effectively or are absent from payment models—in each of the example topics. The gaps are both in the use of available quality measures and in the availability of quality measures linked directly to the medical technologies examined. Measure gaps exist particularly for the timely initiation and use of technologies and engaging in patient-driven shared decision-making about use of the technologies.

- VBP model measure sets incorporate certain intermediate or other outcome measures focused on clinical targets, utilization, or adverse consequences of treatment, such as mortality or complications. While medical technologies can influence these outcomes, measures may not adequately account for the benefits of medical technology over time or other factors, such as outcomes that assess a patient’s functionality or quality of life before and after treatment.

Table 1 provides highlights of specific issues with current VBP models and measure sets related to each medical technology topic, as well as example measure concepts to address gaps.
Table 1. Identified Issues and Measure Concepts to Address Gaps in Value-Based Payment Models

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<th>Medical Technology Topic</th>
<th>Issues in Current VBP Models</th>
<th>Example Measure Concepts to Address Gaps</th>
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| Continuous Glucose Monitoring and Sensor-Augmented Pump Therapy for Type 1 Diabetes | - Models focused on diabetes as a chronic illness do not include measures of priority outcomes (e.g., hyper- or hypoglycemia, amputations) | - Blood Glucose Time in Range (TIR)  
- Patient-Reported TID Quality of Life (QOL) |
| Diagnostic Tests to Prevent Antimicrobial Resistance in Community-Acquired Pneumonia (CAP) | - Lack of measures evaluating whether antibiotics are selected or dosed inappropriately  
- Lack of strong incentives for antibiotic stewardship | - Timely Molecular Assessment of the Pathogen Causing Severe CAP  
- Antibiotic Selection, Dosing, and Duration of Treatment  
- Frequency of Pathogen Identified |
| Hip and Knee Implants for Total Hip and Knee Arthroplasty | - Models do not adequately account for the time horizon associated with the total value of implants  
- Patient-Reported Outcome-Performance Measures (PRO-PMs) are not used effectively in models | - Shared Decision-Making in Implant Selection  
- Patient-Reported Change in Activities of Daily Living  
- Risk-Adjusted Multi-Year Revision Rate |
| Minimally Invasive Colectomy for Inflammatory Bowel Disease | - Post-surgical PRO-PM measures unavailable | - Timely Initiation of Colectomy  
- Patient-Reported Change in QOL Following Colectomy |
| Negative Pressure Wound Therapy for Chronic Wound Care | - Chronic wound care measures focus on pressure ulcers and surgical wounds; other wound types are not represented | - Chronic Wound Infection Rate  
- Patient-Reported Change in Wound Status |
| Prothrombin International Normalized Ratio (INR) Home Testing for Pulmonary Embolism | - Lack of intermediate outcome measures focused on INR for patients on warfarin | - Percentage of Critical INR Values  
- Comparisons of Lab and Home Device Values |
| Stereotactic Body Radiation Therapy (SBRT) for Non-Small Cell Lung Cancer (NSCLC) | - Cancer VBP models do not assess quality of lung cancer treatment  
- Important oncology indicators (survival, tumor control, patient QOL) are missing | - Medically Inoperable Patients Receiving SBRT/Stereotactic Ablative Radiation (SABR)  
- Risk-Adjusted NSCLC Survival Rate |
| Telehealth and Remote Patient Monitoring (RPM) for Heart Failure | - Lack of structural measures assessing utilization of RPM interventions in chronic illness | - Patient Education Provided for RPM  
- Rate of Enrollment in RPM Telehealth Services for Chronically Ill Patients |

In addition to the findings for each specific medical technology topic, high-priority cross-cutting measure gaps that impacted multiple types of medical technologies were also identified. Cross-cutting measures play an important role in accountability programs, as they can assess important performance issues that impact large populations of patients and can reduce the overall number of measures in a program and the accompanying provider burden.
Looking across the topics, Discern examined issues where existing cross-cutting measures could be improved and new cross-cutting measures could be developed to better assess multiple types of technologies for multiple conditions. Cross-cutting measure gaps identified included:

- Gaps in patient-centered measures, including patient experience measures that assess the state of treatment planning and shared decision-making about treatment options and how medical technology is used, and patient-reported outcome (PRO) performance measures (PRO-PMs) that assess change in health status or quality of life.

- Gaps in measures assessing the utilization of health care services, such as assessments of unnecessary hospital utilization. These included hospital intensive care unit length-of-stay measures and measures assessing unplanned re-operation rates.

- Surgical measure gaps, including post-surgical functional status, infection rates, and shared decision-making measures that ensure providers communicate the availability of surgical options.

- Gaps in the capture and use of device-reported data, which can include both clinical data points and patient-reported data, and which can be used for both population health assessments and care management for individual patients.

**Recommendations and Action Steps**

This white paper recommends action steps that policymakers, professional societies, public and private payers, medical technology manufacturers, and other stakeholders can take to improve the state of quality measurement for medical technology. Stakeholders should advocate for meaningful measures to fill gaps, and engage experts at device manufacturers in the development, use, and assessment of quality measures in VBP. As a stakeholder with highly specialized clinical expertise related to certain technologies, manufacturers should be more active in the quality measurement development process.
### PRIORITIZE MEASURE GAPS
- Value-based program (or quality measurement) stakeholders—including medical professional societies, patient advocacy groups, government policymakers, and medical technology manufacturers—should work to leverage real-world data to understand where quality gaps exist and how they align with the goals of improving patient and population health and lowering costs.
- Payers, such as CMS and commercial health plans, and quality organizations, such as NQF and NCQA, should use this report and work with each of the stakeholders mentioned above to define measure gap priorities for measure development and work with stakeholders, including manufacturers, to define measure concepts that better reflect the value of medical technology.

### ENHANCE EVIDENCE
- VBP (or quality measurement) stakeholders should collaborate with manufacturers to close evidence gaps, examine the quality of clinical guidelines, and ensure that recommendations promote the evidence-based use of technologies.
- Payers and policymakers should consider the utility of real-world evidence related to the benefits of medical technology when designing VBP models and value-based contracting arrangements.

### DEVELOP NEW MEASURES
- CMS and other payers should prioritize measure development funding for cross-cutting and outcomes-focused measures that align with National Quality Strategy objectives and which also reflect the value of innovative treatments.
- Medical professional societies, data registry owners (including Qualified Clinical Data Registries (QCDRs)), and measure developers should incorporate identified priority measure concepts into measure development planning.
- NQF should engage quality measurement stakeholders—practitioners, patient groups, and medical technology manufacturers—through the NQF Measure Incubator to support development of priority quality measures.

### LEVERAGE EXISTING MEASURES FOR VBP
- Quality measure stewards should collaborate with VBP and quality measurement stakeholders to identify reasons why available measures that could fill gaps in program measure sets are not in program use. Do the measures need to be respecified? Do they need further testing?
- Measure stewards should coordinate with VBP and quality measurement stakeholders to identify opportunities to refine available measures that could fill gaps.
- NQF committees should review the endorsement status of medical technology-focused measures and include manufacturers as a key stakeholder to inform maintenance priorities.
- NQF should engage medical technology manufacturers through the Measure Applications Partnership (MAP) process to prioritize available technology-focused measures of interest for use in Medicare VBP programs.

### INCORPORATE NEW MEASURES IN VBP MODELS
- The Health Care Payment Learning and Action Network (HCP-LAN)\(^3\) and the Physician-Focused Payment Model (PFPM) Technical Advisory Committee (PTAC) should work with medical technology manufacturers to ensure new models reflect the value of innovative technologies\(^4\).
- Measure developers should recommend new priority measures for CMS programs through CMS’ annual call for measures.
- Measure developers should advocate for inclusion of quality measures that reflect the value of medical technology in payer-developed core measure sets, including the CMS/AHIP Core Quality Measure Collaborative (CQMC), which seeks to develop core measure sets aligned across public and commercial VBP programs\(^5\).
- Payers and policymakers should incorporate new measures reflecting the value of innovative medical technologies into VBP models and contracting arrangements; VBP models should further be refined to ensure that episode length and performance year time horizons adequately account for the value that innovative technologies provide to health care.