MEDICAL TECHNOLOGY IN THE VALUE-BASED ENVIRONMENT: AN ASSESSMENT OF QUALITY MEASURE GAPS

DISCERN HEALTH

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GLOSSARY OF TERMS

AACE	American Association of Clinical Endocrinologists
AAFP	American Academy of Family Physicians
AAOS	American Academy of Orthopaedic Surgeons
ACCP	American College of Chest Physicians
ACE	American College of Endocrinology
ACO	Accountable Care Organization
ACS	American College of Surgeons
ADA	American Diabetes Association
AHRQ	Agency for Healthcare Research and Quality
AMR	Antimicrobial Resistance
APM	Alternative Payment Model
ASCQR	Ambulatory Surgical Center Quality Reporting
ATS	American Thoracic Society
BTS	British Thoracic Society
CAP	Community-Acquired Pneumonia
CDC	Centers for Disease Control and Prevention
CDS	Clinical Decision Support
CGM	Continuous Glucose Monitoring
CIED	Cardiovascular Implantable Electronic Device
CJR	Comprehensive Care for Joint Replacement Model
CMMI	Center for Medicare & Medicaid Innovation
CMS	Centers for Medicare & Medicaid Services
CQMC	Core Quality Measure Collaborative
CRT	Cardiac Resynchronization Therapy
EHR	Electronic Health Record
ER	Emergency Room
ERS	European Respiratory Society
ESCMID	European Society for Clinical Microbiology and Infectious Diseases
FFS	Fee-For-Service
HAC-R	Hospital Acquired Condition Reduction Program
HbA1c	Hemoglobin A1c
HCP-LAN	Health Care Payment Learning and Action Network
HHQR	Home Health Quality Reporting Program
HHS	U.S. Department of Health and Human Services
HHVBP	Home Health Value-Based Purchasing Program
HIQR	Hospital Inpatient Quality Reporting Program
HIT	Health Information Technology
HOQR	Hospital Outpatient Quality Reporting Program
HQRP	Hospice Quality Reporting Program
HRRP	Hospital Readmissions Reduction Program
HVBP	Hospital Value-Based Purchasing
IBD	Inflammatory Bowel Disease
ICD	Implantable Cardioverter-Defibrillator
ICHOM	International Consortium for Health Outcomes Measurement
ICU	Intensive Care Unit
IDSA	Infectious Diseases Society of America
INR	International Normalized Ratio
LOS	Length of Stay
LTCHQR	Long-Term Care Hospital Quality Reporting Program
MedPAC	Medicare Payment Advisory Commission
MIPS	Merit-Based Incentive Payment System
MIS	Minimally Invasive Surgery
MNCM	Minnesota Community Measurement
MSSP	Medicare Shared Savings Program
NCCN	National Comprehensive Cancer Network
NCQA	National Committee for Quality Assurance
NGACO	Next Generation ACO Model
NHQI	Nursing Home Quality Initiative
NHSN	National Healthcare Safety Network
NIH	National Institutes of Health
NPWT	Negative Pressure Wound Therapy
NQF	National Quality Forum
NSCLC	Non-Small Cell Lung Cancer
OCM	Oncology Care Model
PCHQR	Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program
PCR	Polymerase Chain Reaction
PE	Pulmonary Embolism
PFPM	Physician-Focused Payment Model
PIDS	Pediatric Infectious Diseases Society
PQRS	Physician Quality Reporting System
PRO	Patient-Reported Outcome
PROMIS	NIH's PRO Measurement Information System
PRO-PM	Patient-Reported Outcome Performance Measure
PT	Prothrombin Time
PTAC	PFPM Technical Advisory Committee
QCDR	Qualified Clinical Data Registry
QOL	Quality of Life
QPP	Quality Payment Program
RPM	Remote Patient Monitoring
RSV	Respiratory Syncytial Virus
RT	Radiation Therapy
SABR	Stereotactic Ablative Radiotherapy
SAP	Sensor-Augmented Pump
SBRT	Stereotactic Body Radiation Therapy
SNFQR	Skilled Nursing Facility Quality Reporting Program
SNFVBP	Skilled Nursing Facility Value-Based Purchasing Program
T1D	Type 1 Diabetes
T2D	Type 2 Diabetes
THA	Total Hip Arthroplasty
TIR	Time in Range
TKA	Total Knee Arthroplasty
TTR	Time in Therapeutic INR Range
USWR	U.S. Wound Registry
VBP	Value-Based Payment

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.[1] 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.

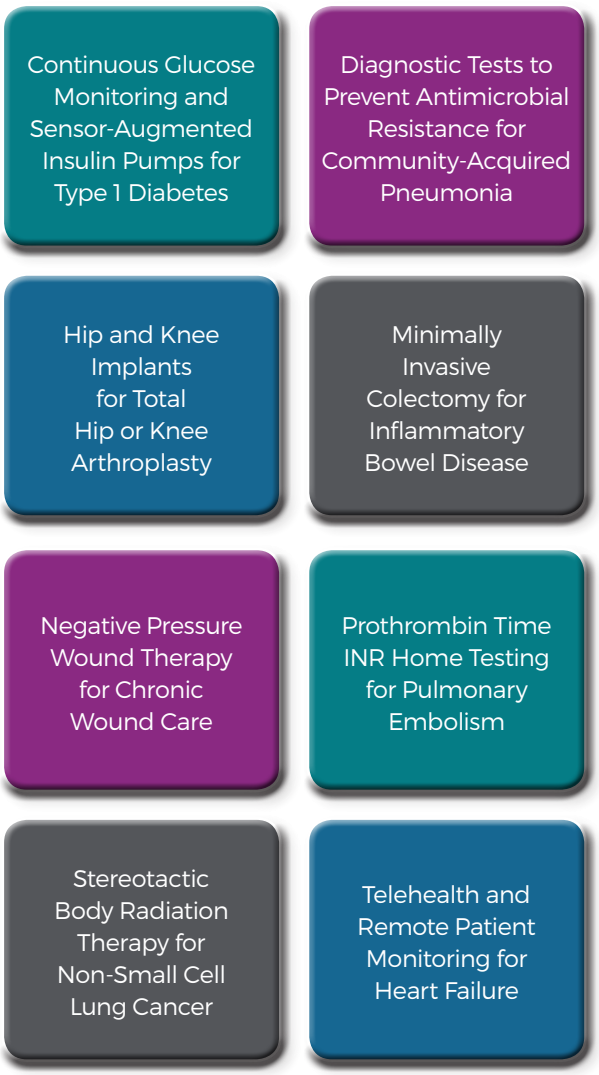
Medical Technology-Related Quality Measure Gaps

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.

Figure 1. Selected Medical Technology Topics



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

Medical Technology Topic	Issues in Current VBP Models	Example Measure Concepts to Address Gaps
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 T1D 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

PURPOSE

This white paper explores quality measure gaps in value-based delivery and payment models for a set of illustrative medical technologies associated with specific clinical topics, and discusses the implications of these gaps in the context of value-based payment (VBP). Further, the paper provides recommendations for stakeholders interested in medical technology to improve quality measurement in VBP models.

BACKGROUND

Value-Based Care in the United States

What Is Value-Based Care?

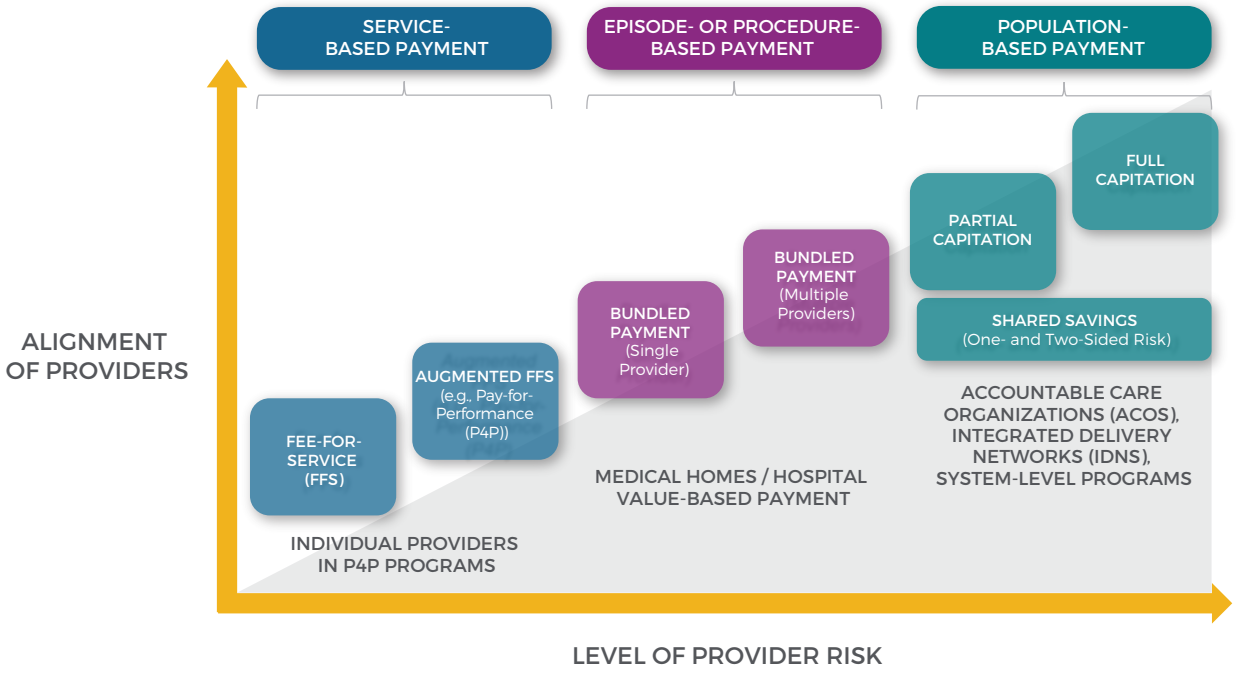
"Value-based care" refers to models that are designed to improve quality and reduce costs by incentivizing providers to deliver high-quality, rather than high-volume, health care.[6] Provider payment in health care is rapidly shifting from volume-based, provider-driven fee-for-service (FFS) to alternative models of VBP and patient-centered care delivery.

The degree to which Medicare payment has been linked to quality has risen quickly over the past three years, with more beneficiaries being served by models that tie payment to value. This number is anticipated to increase as the Centers for Medicare & Medicaid Services (CMS) and its Innovation Center (CMMI) develop and test new voluntary programs and models for payment.[7] Commercial payers have followed closely, contributing to a rising number of shared savings contracts with accountable care organizations (ACOs),[8] as well as innovative episode and bundled payment arrangements with hospitals and other providers.[9]

Types of Value-Based Payment Models

VBP models create new incentives for providers to improve quality and lower cost. The degree of risk providers share with payers varies depending on the model. Figure 2 illustrates types of VBP models on a continuum of increasing risk and alignment among providers. Appendix A includes a summary of various types of VBP incentives in use by Medicare, Medicaid, and commercial payers.

Figure 2. Value-Based Payment Continuum



As the level of provider risk increases under VBP models, the focus on patient experience, population health, and appropriate and effective care becomes more acute.

The Role of Medical Technology in Value-Based Care

Medical technologies are an essential component of health care delivery, providing innovations that improve a variety of services including diagnostics, treatments (such as surgery or other procedures), analytics, and patient monitoring. As technology evolves, it offers the opportunity to improve patient quality of life and life expectancy, replace expensive procedures with less risky and lower-cost alternatives, reduce hospital admissions and length of stay, and reduce health care spending over time.

Effective use of medical technologies promotes the triple aim of value-based care: better care, healthier people and communities, and lower costs.[10] For example, the use of insulin pumps, which can improve clinical outcomes such as glucose control and reduction of hypoglycemic events while reducing patient disease burden, has been shown to generate annual savings of more than $5,000 per patient.[11,12] It is imperative that as adoption of VBP increases, these models recognize and reward appropriate use of medical technology.

Evolution from Volume to Value-Based Payment

Since the passage of the Patient Protection and Affordable Care Act in 2010, CMS has sought to develop and test new VBP models. These programs include:

- Shared savings models, including the Medicare Shared Savings Program (MSSP) for ACOs;
- Demonstration models tested under the scope of the scope of CMMI, which include ACO models with increasing opportunities to share in savings, and episode-based payment models that test providers' ability to reduce costs against a benchmark price for a procedure or treatment episode. Episode-based models include the Bundled Payment for Care Improvement (BPCI) Initiative and Comprehensive Care for Joint Replacement (CJR);
- Hospital payment models that incentivize quality reporting, improved care and safety outcomes, and reduction in unnecessary utilization, including readmissions and avoidable complications; and
- Facility-based quality reporting programs, including programs for ambulatory surgery centers and post-acute care facilities.

For clinicians, the recently implemented Medicare Quality Payment Program (QPP) consolidates previous clinician payment programs, including the Physician Quality Reporting System (PQRS), Electronic Health Record (EHR) Incentive Program for Eligible Professionals (Meaningful Use) and Value-Based Payment Modifier (VBPM), into one comprehensive program called the Merit-Based Incentive Payment System (MIPS). It also creates additional incentives for clinicians to participate in alternative payment models (APMs) that require more risk, with the goal of increasing coordination among providers and linking more payment to VBP models. Further, CMS' priorities[1] for measure development and alignment, focused on patient-centered

outcomes, create an opportunity for gap analysis findings to inform the use of more meaningful and efficient measurement. This is particularly important for new specialty APMs that integrate value-based decision-making for devices and other technologies.

As these programs continue to evolve, policymakers should be mindful of ways to structure VBP incentives that promote the evidence-based use of innovative medical technology products. Importantly, program developers should engage manufacturers to understand whether cost incentives and quality measures used in these programs adequately reflect the value of their products in the marketplace.

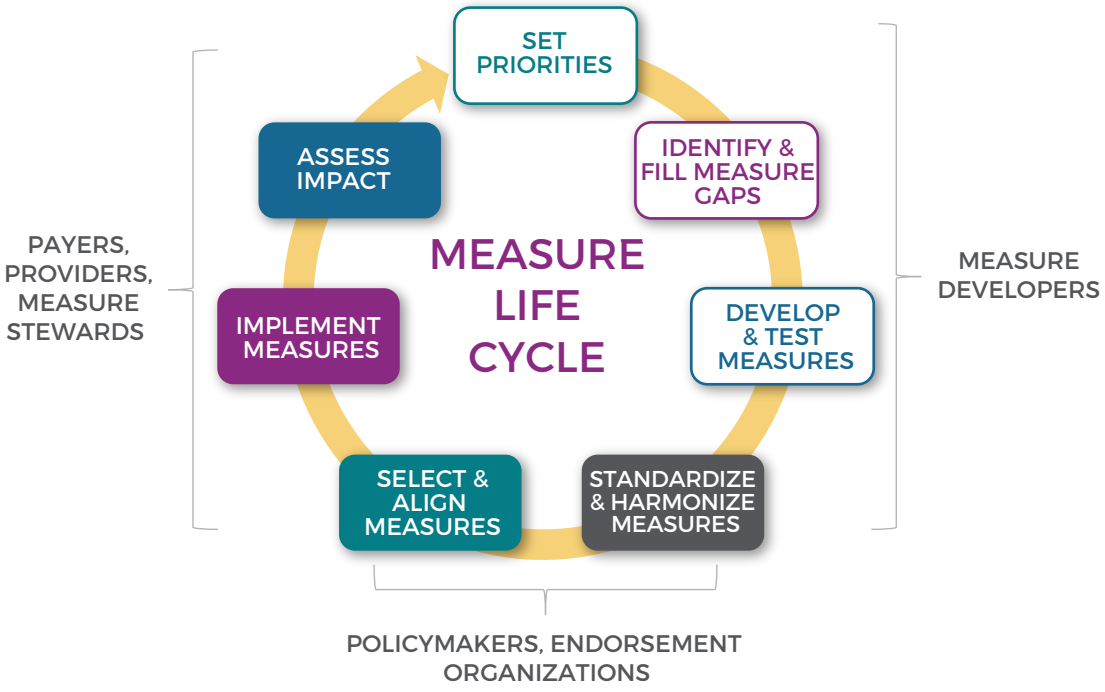
Measuring Quality

Quality measures are tools that payers, providers, and other stakeholders use to quantify aspects of care delivery such as processes, outcomes, patient perceptions, and organizational structures or systems. Quality measures used in Federal and commercial payment programs typically relate to defined quality goals for health care delivery: to be effective, safe, efficient, patient-centered, equitable, and timely.[13]

Developing and Implementing Quality Measures

Quality measures used in VBP models follow a continuous cycle of prioritization, conceptualization, development, endorsement, selection, use, and assessment of impact. Figure 3 illustrates this cycle.

Figure 3. Quality Measurement Life Cycle



Stakeholders, including clinicians, payers, policymakers, patient advocates, and manufacturers, must first set priorities for measurement. Priorities are based on consensus and evidence-based practice recommendations for appropriate care delivery, areas where performance gaps exist, and whether the identified issues address a high-priority national health care goal, significant population, or impactful morbidity.

Once priorities are defined, measure developers such as medical professional societies or quality organizations (e.g., the National Committee for Quality Assurance (NCQA)) work to identify areas where measures are not available but are needed, and conceptualize, specify, and test new quality measures. The process for specifying measures is nuanced and requires consideration of data sources, target populations, and the level of analysis at which measures should be applied. Testing is required to ensure that measures are valid and reliable.

Once measures are developed, they may be submitted for endorsement to the National Quality Forum (NQF). NQF examines measures against desirable attribute criteria, including assessing a measure's importance, scientific soundness (i.e., validity and reliability), feasibility, and usefulness. NQF also helps to ensure that new measures are harmonized with existing measures that may assess similar facets of care.

Policymakers then assess which measures are needed for program measure sets. Once measures are implemented, providers report data and may be scored on their performance. Over time, the impact of measures should be assessed to determine whether they are providing meaningful feedback about quality of care and whether they are potentially causing unintended consequences.

The cycle then repeats, with an evaluation of the measure's impact and refinement of priorities for improvement. It is important that various entities that have roles in the cycle consider innovative technologies at each step; otherwise, quality measures used for VBP models can have the effect of freezing innovation in place.

Medical technology manufacturers should be mindful of the steps in the cycle and opportunities for engagement at each step. For example, a manufacturer may work with a measure developer to share data on performance variation or evidence for a high-priority measure opportunity. Manufacturers may also work through a mechanism like the NQF Measure Incubator to provide grant funding for developing and testing measures. Finally, manufacturers may engage payers and the NQF through submission of public comments or participation in technical expert panels on specific quality measurement issues.

Types of Quality Measures

Measures assess various aspects of care and may be used for multiple purposes. Table 2 presents the various types of measures in use in VBP models, and provides examples of NQF-endorsed measures of each type relevant to certain medical technologies.

Table 2. Quality Measure Types[14,15,16]

Type	Description	Example Measure	Relevant Technology
Structural	Reflects the conditions under which providers care for patients	Participation in a Systematic National Dose Index Registry NQF 0740 [American College of Radiology]	Radiation therapy (establishes national dose index benchmarks for designated examinations)
Process	Assesses whether care delivery steps are followed	Thorax Computed Tomography (CT) – Use of Contrast Material NQF 0513 [CMS]	Computed tomography imaging technology (promotes review and benchmarking of radiation and contrast doses in imaging)
Intermediate Outcome	Assesses a change produced by an intervention that leads to a longer-term outcome	Hemoglobin A1c (HbA1c) Poor Control (>9.0%) NQF 0059 [National Committee for Quality Assurance]	Continuous glucose monitoring and insulin pumps (assesses whether patients are not meeting glycemic targets that can contribute to long-term adverse health consequences)
Outcome	Assesses a change in the health state of a patient resulting from care delivery	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) NQF 1550 [CMS]	Hip and knee implants (assesses complications associated with surgeries up to 90 days after the procedure)
Patient Experience	Records patient perspectives on the provision of their care	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) NQF 0166 [CMS]	Hospital-delivered technologies such as imaging, radiotherapy, or surgical tools (assesses patient experience with hospital services)
Patient-Reported Outcome (PRO)	Reports the status of a patient's health condition directly from the patient without interpretation of response by a clinician	Average Change in Functional Status Following Total Knee Replacement Surgery NQF 2653 [Minnesota Community Measurement]	Hip and knee implants (assesses improvement in pain and mobility following surgery)
Cost / Resource Use	Assesses monetary or resource units expended by a provider to deliver health care services	Episode Treatment Groups (ETG) Based Hip/Knee Replacement Cost of Care Measure NQF 1609 [Optum]	Hip and knee implants (evaluates the cost of a hip or knee replacement treatment episode)

Role of Quality Measures

Quality measures play an important role in VBP models, as they allow payers to hold providers accountable for quality, and assist providers in identifying opportunities for improvement and monitoring progress over time. Quality measures are built based on their alignment with stakeholder objectives, impact on patient populations, variation in clinical practice and cost, linkage to important health outcomes, and feasibility of collecting the data used to calculate the measures. Specifically, measures can serve various purposes, depending on the user:

- **Promoting Appropriate Care Delivery:** Measures balance VBP financial incentives by linking payment to improvements in quality, ensuring that cost containment does not lead to worse patient outcomes or underuse of services, including innovative treatments and technologies.
- **Monitoring System and Practice Quality Improvement:** Measures help providers identify opportunities to improve clinical care and outcomes.
- **Facilitating Transparency for Patients and Health Care Purchasers:** Measures communicate quality to patients, health care purchasers, and other stakeholders, which drives competition and informs provider selection.

Measuring performance may help drive quality improvement over time. Data from HealthPartners health plan shows that members receiving Optimal Diabetes Care, as defined and measured by Minnesota Community Measurement, saw improvements in clinical outcomes such as eye complications, kidney disease, leg amputations, and acute myocardial infarctions (MIs).[17] Measuring performance may also help drive appropriate delivery of services and therapy. NCQA has shown that during a 10-year period of health plan-level reporting of its measure of beta-blocker use following hospital discharge for MI, nationally reported rates of prescribing moved from 62% to 96.6%.[18]

Risks Associated with Measure Gaps for Medical Technology

Quality measures help balance the financial incentives for cost containment in VBP models. If quality measures do not effectively assess the processes and outcomes associated with good care delivery, there is an inherent risk for unintended consequences. Specifically, this may include:

- Overuse or underuse of services, particularly where the value of outcomes associated with a costlier service is not recognized under the model's incentives
- Safety issues, where a less effective, but less expensive, service or therapy is 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.

"Gaps" in measurement may include: (1) areas where quality measures have not been developed and are not available or (2) areas where quality measures are currently available but are not in use in payment programs. This white paper analyzes both categories of gaps in the context of selected medical technology examples.

Other Strategies for Improving Quality in Value-Based Care

It is important to recognize that quality measures are not the only tools available to improve the quality of care, and other approaches may have implications for the appropriate use of medical technology. Patient-centered strategies for improved care coordination, population management, team-based care, and information exchange or meaningful use of health information technology (HIT) have moved to the forefront as ways to improve quality and achieve success under VBP models. These strategies may be enhanced by HIT solutions such as clinical decision support and integrated EHRs that help providers adhere to evidence-based clinical practice and implement population-level interventions.

These strategies may be recognized in VBP models when payers incentivize patient-centered primary care, specialty care, or integrated delivery systems. For example, under MIPS, CMS offers financial benefits for providers who attest to performing certain clinical practice improvement activities. Similar to quality measures, patient-centered transformation and improvement activities often align with the benefits that medical technology can provide. As such, Discern analyzed MIPS clinical practice Improvement Activities in parallel with the analysis of quality measures for the purposes of this review.

METHODOLOGY

Overview

To explore quality measure gaps impacting medical technology, we completed the following gap analysis process:

- Identify a narrow set of illustrative topics that include: (1) a medical technology and (2) a clinical area for which the medical technology is commonly used;
- Identify a representative set of VBP model measure sets against which to assess quality measure gaps; and
- Apply a research logic model to each topic to examine gaps in measurement and gaps in VBP model measure sets, and assess the results of the analysis across all the topics to identify cross-cutting priorities for measurement.

To validate our findings, we conducted targeted discussions on each topic with clinical subject matter experts from medical technology organizations. We incorporated feedback from these discussions into our overall findings.

Topic Selection

To establish our topics for analysis, we defined the following criteria for assessing medical technologies. Technology topics met one or more of the following:

- Technologies used to treat:
  - High-cost illnesses[19,20]
  - High-mortality illnesses or illnesses with high complication rates[21,22]
  - Chronic illnesses[23]
  - High-impact Medicare illnesses[24]
- Technologies that are:
  - Used in frequent or costly procedures[25]
  - High-cost supply items[26]
  - High-cost capital expenditures[27]

Medical technologies are frequently used in treating more than one condition. To narrow our focus, we identified a prevalent or costly clinical area for each medical technology.

Finally, to ensure that our list of selected topics was representative of the medical technology sector overall, we selected topics that cover six categories: (1) Capital Equipment; (2) In Vitro Diagnostics; (3) Durable Medical Equipment; (4) Implant Technology; (5) Surgical and Recovery Tools; and (6) Telehealth.

The selected illustrative topics, including the categories and types of medical technology and the associated clinical focus areas that were the focus of our analysis, are listed in Table 3 below. Refer to Appendix B for details of the medical technology topic selection.

Table 3. Selected Medical Technology Topic Areas

Category	Technology	Clinical Focus
Durable Medical Equipment	Continuous Glucose Monitoring (CGM) and Sensor-Augmented Insulin Pumps (SAP)	Type 1 Diabetes (T1D)
In Vitro Diagnostics	Diagnostic Tests to Prevent Antimicrobial Resistance (AMR)	Community-Acquired Pneumonia (CAP)
Implant Technology	Hip and Knee Implants	Total Hip / Knee Arthroplasty
Surgical and Recovery Tools	Laparoscopic Tools / Minimally Invasive Surgery (MIS)	Inflammatory Bowel Disease (IBD)
	Negative Pressure Wound Therapy (NPWT)	Chronic Wound Care
Durable Medical Equipment	Prothrombin Time (PT) International Normalized Ratio (INR) Home Testing	Pulmonary Embolism (PE)
Capital Equipment	Stereotactic Body Radiation Therapy (SBRT)	Non-Small Cell Lung Cancer (NSCLC)
Telehealth	Telehealth and Remote Patient Monitoring (RPM)	Heart Failure

Representative VBP Measure Sets

To examine gaps at the measure set level, we identified representative VBP models for which financial incentives could impact the use of medical technology. For each model, we examined the quality measures providers must report and included the results in our topic-specific findings. For each topic, we identified gap areas within applicable model measure sets. Table 4 summarizes the models that apply to medical technology topic areas.

Some models were "generally applicable," meaning they impacted all, or nearly all, medical technologies under review, and some models were "specifically applicable," meaning they impacted a subset of the medical technologies under review. For example, the Medicare QPP for clinician payment is inclusive of a wide range of primary care and specialty providers who use the full list of medical technologies, whereas the Oncology Care Model (OCM) only assesses care for patients with cancer and would likely only apply to the SBRT medical technology topic.

Table 4. Representative VBP Models by Medical Technology Topic

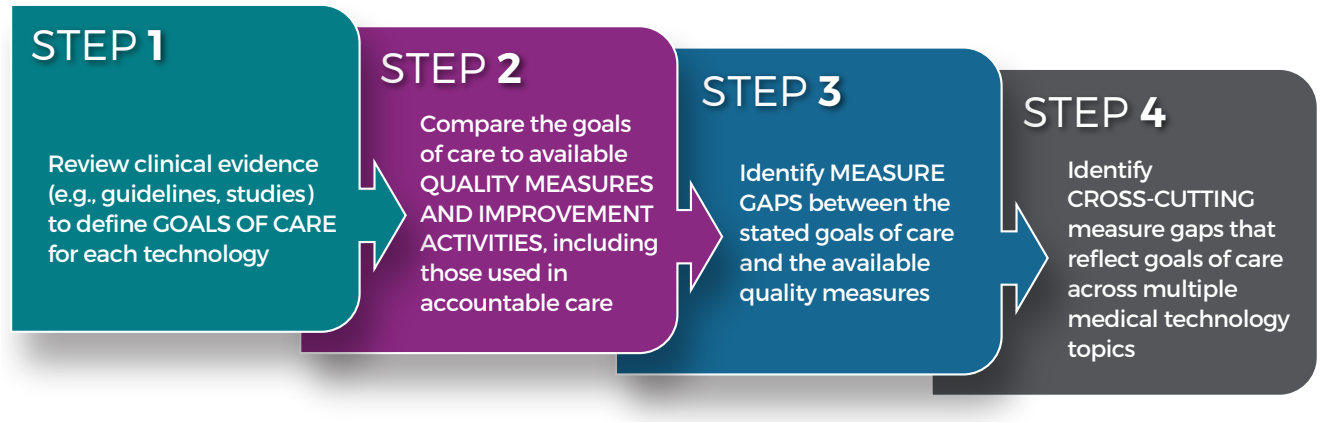
Medical Technology Topic	Specifically Applicable VBP Measure Sets	Generally Applicable VBP Measure Sets
Continuous Glucose Monitoring (CGM) and Sensor-Augmented Insulin Pumps (SAP) for Type 1 Diabetes (T1D)	■ No specific models applicable	■ Bundled Payment for Care Improvement (BPCI) Initiative ■ Comprehensive Primary Care (CPC) / Plus (CPC+) ■ Hospital Inpatient Quality Reporting (HIQR) Program ■ Hospital Outpatient Quality Reporting (HOQR) Program ■ Hospital Value-Based Purchasing (HVBP) Program ■ Medicare Shared Savings Program (MSSP) / Next Generation ACO (NGACO) Model ■ Merit-Based Incentive Payment System (MIPS)
Diagnostic Testing to Prevent Antimicrobial Resistance (AMR) for Community-Acquired Pneumonia (CAP)	■ Hospital-Acquired Condition Reduction (HACRP) Program	
Hip and Knee Implants	■ Hospital Readmissions Reduction Program (HRRP) ■ Comprehensive Care for Joint Replacement (CJR) Model ■ Surgical Hip and Femur Fracture Treatment (SHFFT) Model	
Minimally Invasive Colectomy for Inflammatory Bowel Disease (IBD)	■ Ambulatory Surgical Center Quality Reporting (ASCQR) Program	
Negative Pressure Wound Therapy (NPWT)	■ Home Health Quality Reporting (HHQR) Program ■ Home Health Value-Based Purchasing (HHVBP) Program ■ Long-Term Care Hospital Quality Reporting (LTCHQR) Program ■ Nursing Home Quality Initiative (NHQI) ■ Skilled Nursing Facility Quality Reporting (SNFQR) Program ■ Skilled Nursing Facility Value-Based Purchasing (SNFVBP) Program	
Prothrombin Time (PT) International Normalized Ratio (INR) Home Testing	■ HHQR ■ HHVBP ■ HRRP	
Stereotactic Body Radiation Therapy (SBRT) for Non-Small Cell Lung Cancer (NSCLC)	■ Hospice Quality Reporting Program (HQRP) ■ Oncology Care Model (OCM) ■ Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) Program	
Telehealth and Remote Patient Monitoring (RPM) for Heart Failure	■ HHQR ■ HHVBP ■ HRRP	

For a full list and summary of representative VBP measure sets and incentives, refer to Appendix C.

Research Logic Model

To conduct a gap analysis for each medical technology topic, Discern Health employed a multi-step research logic model (see Figure 4).

Figure 4. Medical Technology Gap Analysis Logic Model



Our execution of the research logic model is described below:

STEP 1	Discern Health identified clinical practice guidelines relevant to each technology topic and clinical area using the Agency for Healthcare and Research Quality's (AHRQ) National Guidelines Clearinghouse (NGC). For each of the relevant guidelines, Discern Health identified the recommended goals of care that are relevant to the medical technology. Based on these goals of care, Discern Health identified measurement opportunities for each topic.
STEP 2	Using the results from Step 1, Discern Health identified where quality measures align with opportunities. To identify quality measures, Discern Health reviewed the representative VBP model measure sets using the CMS Measure Inventory and scanned other sources for available measures, including the NQF Quality Positioning System (QPS), the AHRQ National Quality Measures Clearinghouse (NQMC), and relevant medical professional society measures. To identify MIPS Improvement Activities, Discern reviewed the list of available activities in Performance Year 2017 provided in the QPP Final Rule.
STEP 3	Discern Health identified measure gaps, or areas where measurement opportunities are not assessed by VBP measure sets and/or other available measures. Gap opportunities represent areas where existing measures may be used to improve measure sets or where further measure development is needed.
STEP 4	Discern Health identified cross-cutting measure gaps that reflect goals of care across multiple medical technology topics and associated conditions. Once all topics were reviewed, Discern Health identified common issues and measurement opportunities to inform solutions for addressing multiple measure gaps.

Pursuing this logic model allowed Discern Health to capture the following information:

- Clinical guidelines relevant to the use of the technology
- Recommendations for use of the technology in clinical practice
- Benefits of the technology
- Potential measurement opportunities based on evidence and recommendations
- Available quality measures relevant to each medical technology and clinical focus

FINDINGS

This section provides a summary of the findings for each medical technology topic, including an overview of the technology and clinical area of focus, a summary of the measurement opportunities identified for each topic, the current state of the quality landscape, and potential gaps relevant to each medical technology that should be explored for development and implementation to improve VBP programs. The summary also includes cross-cutting gaps that cover multiple medical technology topics. Specific detail, including the resources reviewed and quality measures and gap information for each of the topics, is provided in Appendix D.

Continuous Glucose Monitoring and Sensor-Augmented Insulin Pumps for Type 1 Diabetes

TYPE OF TECHNOLOGY
Durable Medical Equipment

TYPE 1 DIABETES PREVALENCE
Impacts 1.25 million patients, with 29 million people in the U.S. affected by diabetes generally

Continuous glucose monitoring (CGM) and sensor-augmented insulin pumps (SAPs) are technologies used to guide and improve the management of diabetes. Pumps allow insulin therapy to be adjusted based on CGM readings, including suspending insulin injections. These technologies benefit patients by offering automated management that reduces stress and decreases the risk for adverse events and hospitalization.

CGM systems measure glucose levels in real time throughout the day and night using a small sensor inserted beneath the patient's skin, which measures glucose values in the tissue fluid. A wearable display device notifies patients if glucose is nearing a high or low threshold. Insulin pumps administer insulin subcutaneously, and can be configured to adjust based on alerts from CGM.[28] Pumps typically include the device itself, which consists of controls, a processing module, and batteries; a disposable reservoir for insulin; and a disposable infusion set with tubing for the delivery of insulin.[29,30] Both CGM and SAPs offer alternatives to usual finger stick glucose monitoring and injection-based insulin delivery. While current technology still relies on some manual monitoring, closed-loop systems, or "artificial pancreas" technologies, are in development to allow for complete automation of monitoring and delivery.[31]

Type 1 Diabetes and Insulin Therapy

Diabetes mellitus type 1 is a metabolic disorder in which patients do not produce enough insulin, resulting in high blood sugar levels, and is diagnosed by testing hemoglobin A1c (HbA1c) levels. Type 1 Diabetes (T1D) is not preventable, and patients must receive insulin to avoid serious complications and survive.[32] Diabetes (including both T1D and Type 2 Diabetes (T2D)) is highly prevalent, affecting over 29 million people in the U.S. Approximately 1.25 million children and adults have T1D. Diabetes, inclusive of T1D and T2D, is the seventh leading cause of death in the U.S. in 2010.[33]

Treatment for T1D involves lifestyle changes, including diet and exercise, and administration of insulin to manage blood sugar to normal ranges. Types of insulin may vary from rapid- to long-acting, depending on the patient's needs. Insulin delivery and management are coupled with close monitoring of both carbohydrates in food and blood glucose levels. Serious complications can result from inappropriate management. High blood sugar levels can lead to diabetic ketoacidosis, which can result in coma or death; conversely, mismatching insulin, food, and exercise can lead to low blood sugar levels (called hypoglycemia). While hypoglycemia is common, severe hypoglycemia can necessitate hospitalization and further treatment. Longer-term consequences of poor management can include kidney disease, blindness, cardiovascular issues, and neuropathy leading to traumatic lower extremity amputations.

Continuous Glucose Monitoring and Sensor-Augmented Pumps for Type 1 Diabetes Treatment

CGM and SAPs are options for both insulin delivery and close monitoring in certain patients with T1D. While pump-therapy plays a role in management of patients with T2D who require insulin, our analysis focused on the quality issues associated with T1D patients, who require insulin therapy as a core treatment modality to manage their illness. The American Diabetes Association (ADA), the American Association of Clinical Endocrinologists (AACE), and the American College of Endocrinology (ACE) make the following recommendations:[34,35]

- Use of CGM with intensive insulin regimens is recommended to lower HbA1c in adults with T1D
- Intensive management through pump therapy and CGM is recommended and should be strongly encouraged as an approach to glycemic treatment
- CGM should be considered for patients with T1D and T2D on basal-bolus therapy
- Insulin pump therapy should only be used in patients who are motivated and knowledgeable in diabetes self-care, including insulin adjustment

The ADA, AACE, and ACE's clinical recommendations are based on high-quality evidence. Specifically, cited studies identified benefits for both CGM and SAPs that include durable and rapid reduction of HbA1c levels, increased length of time of glycemic control, improvement in managing hypoglycemia resulting in fewer hypoglycemia episodes, and delayed onset and progression of illness.

Type 1 Diabetes Quality Landscape

Discern Health identified several opportunities for measurement within the T1D care episode. These included opportunities for diagnosis (collection of family history, assessment of body mass index (BMI), and timely testing (HbA1c, LDL-C, and blood pressure)), treatment (delivery of education and lifestyle counseling, prescribing intensive insulin regimens, timely prescribing and treatment of hypoglycemia with glucagon), monitoring (assessing blood glucose monitoring, performing HbA1c tests, monitoring BMI, monitoring long-term issues (nephropathy, neuropathy, etc.)), outcomes (complication rates including hypo- and hyperglycemia events, patient-reported quality of life, glycemic control and time in range (TIR)), and structural improvements (testing and maintaining device competency, collecting device-reported patient data). The full list of measurement opportunities is detailed in Appendix D.

Through its scan, Discern Health found numerous quality measures related to diabetes. Diabetes has been a significant focal point for quality improvement, as it is a priority chronic condition with clear clinical targets for management. Existing quality measures covered a range of the measurement opportunities that Discern Health identified, and applied to both T1D and T2D populations. Specifically, NCQA and Minnesota Community Measurement (MNCM) have developed suites of measures to assess appropriate testing and monitoring (HbA1c and blood pressure), and intermediate outcomes associated with this testing (HbA1c and blood pressure control). In addition, there are several adherence-based measures that assess possession ratios for oral anti-diabetic medications (used to treat T2D) and statins (used to manage cholesterol).

Among the larger group of diabetes measures, Discern Health identified 14 measures and 3 MIPS Improvement Activities that are particularly relevant to T1D and the use of CGM and SAP. These measures assess processes such as HbA1c testing for both adult and pediatric patients with diabetes and monitoring for evidence of blood glucose testing for patients receiving insulin. They also included outcomes such as control against glycemic targets, hypo- and hyperglycemic event rates, short-term and long-term complication admission rates, and uncontrolled diabetes admission rates and all-cause pediatric readmission rates. Discern Health did not identify quality measures that focus solely on patients with T1D.

Federal VBP models have made diabetes care process and outcome measurement a priority, due to the high cost and significant burden of the condition. Physician reporting programs, including MIPS, include several measures for blood pressure and LDL-C testing and intermediate outcomes assessing poor glycemic control. The Medicare ACO programs, including MSSP and Next Generation ACO Model (NGACO), include several measures relevant to diabetes: a composite measure of diabetes eye exams and poor glycemic control (>9%), as well as measures of admissions for patients with diabetes and admissions for patients with multiple chronic conditions (including diabetes). The full list of relevant quality measures and their use in VBP models is included in Appendix D.

Remaining Measure Gaps

While diabetes has been a significant area of focus for quality measurement, gaps in measures and measure sets remain. Table 5 summarizes a list of available measures not used in Medicare VBP models, and measure concepts identified by Discern that, if used in VBP models, would help guide appropriate care of patients with T1D, including appropriate use of CGM and SAP.

Table 5. Type 1 Diabetes CGM and SAP Priority Measure Gaps

Domain	Availability	Title	Type	Level of Analysis
Monitoring	Existing *(gap in program measure sets)*	Adult(s) Taking Insulin with Evidence of Self-Monitoring Blood Glucose Testing	Process	Clinician / Facility / Health Plan / Population
Treatment	Concept *(gap for measure development)*	Intensive Insulin Therapy (CGM / SAP) Prescribing	Process	Clinician
Outcome	Concept *(gap for measure development)*	Blood Glucose Time in Range (TIR)	Outcome	Clinician / Facility / Health Plan
	Existing *(gap in program measure sets)*	Glycemic Control – Hyperglycemia	Outcome	Facility
	Existing *(gap in program measure sets)*	Glycemic Control – Hypoglycemia	Outcome	Facility
	Existing *(gap in program measure sets)*	Diabetes Short-Term Complications Admission Rate	Outcome	Population
	Existing *(gap in program measure sets)*	Diabetes Long-Term Complications Admission Rate	Outcome	Population
	Existing *(gap in program measure sets)*	Uncontrolled Diabetes Admission Rate	Outcome	Population
	Concept *(gap for measure development)*	Patient-Reported T1D Quality of Life	PRO	Clinician / Facility
	Concept *(gap for measure development)*	Patient-Reported Incidence of Hypoglycemia	PRO	Clinician / Facility
Structural	Concept *(gap for measure development)*	Patient-Reported Satisfaction with Insulin Delivery Device	PRO	Clinician / Facility
	Concept *(gap for measure development)*	Implementation of Systems to Capture and Utilize Device-Reported Data	Structural	Clinician / Facility

Gaps in Program Measure Sets

As detailed in Table 5, Discern Health identified available measures relevant to the T1D care episode that are not currently used in VBP measure sets:

- While VBP models such as the MSSP incorporate certain quality measures that reflect care or outcomes impacted by appropriate patient management using CGM and insulin pump therapy (such as admissions or readmissions and achievement of glycemic targets), we identified important measures not currently in program use:
  - Outcome measures assessing rates of hyper- and hypoglycemic events ("Glycemic Control – Hyperglycemia" and "Glycemic Control – Hypoglycemia").
  - Outcome measures assessing admissions for short-term complications (ketoacidosis, hyperosmolarity, or coma) and long-term complications (renal, eye, neurological, and circulatory) ("Diabetes Short-Term Complications Admission Rate" and "Diabetes Long-Term Complications Admission Rate").
  - An outcome measure assessing admissions for uncontrolled diabetes without documentation of short- or long-term complications ("Uncontrolled Diabetes Admission Rate").
  - A process measure assessing whether there is evidence for CGM in patients managing diabetes with insulin ("Adult(s) Taking Insulin with Evidence of Self-Monitoring Blood Glucose Testing").

Gaps for Measure Development

There are numerous gaps in available measures related to the use of CGM and SAP for T1D management. Measure concepts that can fill these gaps, and which are detailed in Table 5, include:

- A process measure assessing whether intensive insulin therapy (including paired use of CGM and insulin pump therapy) was prescribed. Because glucose monitoring is an essential factor in determining management of insulin therapy, VBP models should measure the effectiveness with which it is carried out and monitored. Similarly, while measures exist to monitor the provision of, and adherence to, oral anti-diabetic medications, there may be similar opportunities to measure the appropriate prescribing and use of insulin therapy ("Intensive Insulin Therapy (CGM / SAP) Prescribing").
- An intermediate outcome measure assessing blood glucose TIR. While intermediate outcomes in diabetes care have focused on HbA1c levels, this target is based on a snapshot of a patient's glycemic levels at a point in time. More recently, TIR, or the percentage of time that a patient's blood glucose was within normal ranges and thus in control, has been discussed by organizations such as the Juvenile Diabetes Research Foundation as a more appropriate measurement for T1D[36] ("Blood Glucose Time in Range (TIR)").

- Patient-reported outcome (PRO) performance measures, including quality of life and patient-reported change in less severe hypoglycemic event incidence, which does not always result in hospital admission and may be underreported. Quality of life measures are particularly important where the stress of managing insulin injections and monitoring can be alleviated using CGM and/or SAP ("Patient-Reported T1D Quality of Life" and "Patient-Reported Incidence of Hypoglycemia").
    - Development of effective and meaningful PRO tools is challenging, and the benefit of assessing these outcomes should be weighed carefully. PRO performance measures require significant risk adjustment to ensure providers are not misattributed poor outcomes of care beyond their control. Notably, diabetes-specific quality of life survey instruments exist, and could be leveraged for a PRO-PM.
- Structural measure concepts assessing a provider's ability to leverage CGM or pump device reported data. This may include clinical data points, such as blood glucose levels or shifts in insulin dosing that can inform care management, or patient-reported data on satisfaction or symptoms ("Patient-Reported Satisfaction with Device"). Structural measures are also needed to drive appropriate utilization of this data in care management ("Implementation of Systems to Capture and Utilize Device-Reported Data").

Diagnostic Testing to Prevent Antimicrobial Resistance for Community-Acquired Pneumonia

Antimicrobial resistance (AMR) refers to the ability of microbes to resist the effects of medications used to treat them. Resistance can develop to antibacterials, antifungals, antivirals, and anti-parasitic agents. Antibiotic resistance applies specifically to agents used to treat bacterial infections. AMR may result from both appropriate use and misuse of antimicrobials, although misuse is a greater threat to long-term availability of effective agents. Overuse of antibiotics can cause otherwise harmless bacteria to develop resistance to multiple antibiotics, rendering once-effective treatment ineffective.[37]

TYPE OF TECHNOLOGY
In Vitro Diagnostics

PNEUMONIA PREVALENCE
Eighth leading cause of death in combination with influenza in the U.S., with 4-5 million cases annually

Rapid and accurate diagnostic tests, including laboratory and point-of-care tests, are necessary to identify the microbial etiology of the infection, allowing providers to select more targeted therapy. Use of targeted therapy helps decrease development of resistance by lowering environmental pressures for the selection of resistant bacteria. Development of rapid diagnostic assays that identify the specific bacteria or viruses directly from patient specimens is critical. Without definitive pathogen identification, physicians rely on empiric antibiotic therapy as a first line of treatment based on an incomplete understanding of the disease process.

Conventional diagnostic tests for infections include Gram stains, bacterial and fungal cultures, and antimicrobial susceptibility testing, along with imaging studies. Certain biomarkers, including C-reactive protein and procalcitonin, often can help differentiate bacterial from viral infection and thus reduce the duration and frequency of antibiotic therapy.[38,39] Depending on the pathogens, other tests, such as immune serologic tests, rapid urine antigen assays, or direct fluorescent antibody stains may be appropriate, although their sensitivity is often relatively low. More recently, molecular diagnostic testing, including polymerase chain reaction (PCR) and loop-mediated isothermal amplification (also known as "LAMP") assays have been developed and can rapidly and accurately provide a pathogen-specific diagnosis.[40,41,42,43,44]

Community-Acquired Pneumonia and Antibiotic Therapy

Pneumonia is an inflammatory condition of the lungs most often caused by a viral or bacterial infection. Pneumonia can cause coughing, fever, chest pain, shortness of breath, and death in severe cases. Pneumonia, in combination with influenza, is the eighth leading cause of death in the U.S. The incidence of community-acquired pneumonia (CAP) ranges from 4-5 million cases annually, and about one-quarter of the cases require hospitalization.[45,46] For children younger than 2 years old, pneumonia accounts for 13% of all infectious diseases.[47] Microorganisms that cause pneumonia include influenza viruses, *Streptococcus pneumoniae*, and respiratory syncytial virus (RSV). "Atypical" pneumonia, including CAP, often is caused by bacteria, such as *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydia pneumoniae*.[48] CAP refers to infections in patients who have not been in contact with the health care system. Therefore, CAP excludes patients who develop an infection during a hospital stay.

Some forms of CAP can be prevented through appropriate pneumococcal or influenza vaccinations, which can prevent secondary bacterial infections. CAP is primarily treated with antibiotics to aid in eradicating the pathogens. In current practice, diagnostic tests are often not used to guide therapy. Most treatment is empiric, with selection of antibiotics depending on whether CAP is considered "typical" or "atypical." Treatment also depends on the patient's morbidities and whether they are being treated in an inpatient, outpatient, or ICU setting.

Diagnostic Testing for Community-Acquired Pneumonia Treatment

Diagnostic testing should optimally be a core element of pneumonia treatment. However, the current turnaround time for traditional diagnostic tests is often days and, as a result, diagnostics are rarely used.

Recommendations for the use of diagnostics in clinical guidelines vary, as the evidence for new diagnostic technologies is evolving. U.S.-based guidelines from the Infectious Diseases Society of America (IDSA), American Thoracic Society (ATS), and Pediatric Infectious Diseases Society (PIDS),* as well as European-based guidelines from the British Thoracic Society (BTS), National Institute for Health and Care Excellence (NICE), European Respiratory Society (ERS), and European Society for Clinical Microbiology and Infectious Diseases (ESCMID) include recommendations for rapid diagnostic tests:

- IDSA/ATS guidelines recommend using diagnostic tests to identify the etiology of disease; specific pathogens should be investigated where a specific pathogen is suspected or in the presence of clinical indications for more extensive diagnostic testing
- PIDS/IDSA guidelines recommend the use of rapid testing for influenza in children with CAP; children with suspicious signs and symptoms for *M. pneumoniae* should be tested to guide antibiotic selection
- BTS guidelines recommend PCR as the diagnostic method of choice for adult hospitalized, high-severity CAP patients to identify M. pneumoniae, *C. pneumoniae*, and respiratory viruses
- BTS guidelines further recommend microbiological investigations (blood culture, PCR, immunofluorescence, serology, and antigen testing) to determine viral and bacterial pathogens for children with severe CAP
- ERS/ESCMID guidelines recommend application of quantitative molecular testing where available for the detection of *S. pneumoniae*, both in sputum and blood, for CAP patients in whom antibiotic therapy has been initiated; application of molecular tests for the detection of influenza and RSV should be considered during the winter season and for the detection of atypical pathogens, provided the tests are validated and results can be obtained sufficiently rapidly to be therapeutically relevant

Discern Health's review of the literature, along with an assessment of the evidence used to support guideline recommendations, identified benefits of both rapid biomarker determination via culture and PCR, and diagnostic testing yielded highly sensitive and/or specific results and

* The 2007 IDSA/ATS guidelines are anticipated to be updated in 2018.

reduced the time to detection or diagnosis of infection. This resulted in improved prediction of the type of pathogen, more accurate discrimination of viral versus bacterial infections, more accurate selection of narrow-spectrum antibiotics, reduced inpatient and intensive care unit (ICU) admissions, and reduced hospital length of stay.

Community-Acquired Pneumonia Quality Landscape

Discern Health identified numerous quality measurement opportunities within the pneumonia care episode. These included measurement opportunities relevant to prevention (immunization / vaccination, implementation of smoking cessation), diagnosis (risk assessment, timely chest imaging, timely biomarker testing, use of rapid diagnostics to determine viral and bacterial pathology), treatment (antibiotic selection, including use of empiric or pathogen-directed therapy; antibiotic timing; avoidance of overuse), monitoring (assessment and classification of response failure), and outcomes (pneumonia admission and readmission rates, mortality rates, treatment failure rates, hospital length of stay). The full list of measurement opportunities is detailed in Appendix D.

Through its measure scan, Discern Health identified nearly 50 quality measures or activities relevant to the pneumonia treatment episode, or to the use of antibiotics generally. Twenty-eight measures and one MIPS Improvement Activity were indirectly relevant to the use of diagnostic tests to direct therapy.* Discern Health identified diagnostic measures that promoted timely collection of blood culture in hospitalized patients, and assessment of vital signs for all CAP patients. NCQA-developed measures assess avoidance of inappropriate antibiotic use for upper respiratory infections and acute bronchitis, which are often viral and could be mistreated as bacterial CAP.

Three Centers for Disease Control and Prevention (CDC)-developed measures are relevant. These include the National Healthcare Safety Network (NHSN) measures assessing inpatient hospital-onset of methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile* infection (CDI), the former of which can contribute to pneumonia incidence, and the latter of which can result from inappropriate antibiotic treatment for CAP.[49,50] A third NHSN measure assesses general antimicrobial use in hospitals.

Discern Health identified relevant clinical outcome measures assessing rates of mortality following pneumonia admissions, and complications associated with pneumonia, including onset of ventilator-associated pneumonia. Measures of utilization outcomes, including pneumonia-related readmissions, all-cause readmissions, and excess hospital days or general length of stay measures were also identified. Finally, there are multiple episode-based cost measures specific to inpatient pneumonia cases.

Medicare hospital VBP programs, such as the HIQR, HVBP, and HRRP include measures of pneumonia mortality and readmissions following treatment. The HIQR and HVBP programs also require reporting of an "Initial Antibiotic Selection for CAP in Immunocompetent Patients" measure that promotes guidelines adherence for treatment selection. Physician reporting

* Excluded measures assessed preventive care issues, such as appropriate pneumococcal vaccinations or rates of pneumonia admissions, and did not relate to the need for diagnostic testing.

programs, including MIPS, use antibiotic appropriate use measures, such as for pharyngitis, acute bronchitis, and upper respiratory infection. The full list of relevant quality measures and their use in VBP models is detailed in Appendix D.

Remaining Measure Gaps

Discern identified numerous remaining measure gaps. Table 6 summarizes a list of available measures not used in Medicare VBP models, and measure concepts identified by Discern that, if used in VBP models, would guide appropriate care of patients with CAP, including appropriate use of rapid diagnostic testing to direct treatment and prevent AMR.

Table 6. Community-Acquired Pneumonia Diagnostic Testing Priority Measure Gaps

Domain	Availability	Title	Type	Level of Analysis
Diagnosis	Existing *(gap in program measure sets)*	Vital Signs for Community-Acquired Bacterial Pneumonia	Process	Clinician
	Concept *(gap for measure development)*	Risk Severity Screening for Pneumonia Performed	Process	Clinician
	Existing *(gap in program measure sets)*	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital	Process	Facility
	Existing *(gap in program measure sets)*	PN3a – Blood Cultures Performed Within 24 Hours Prior to or 24 Hours After Hospital Arrival for Patients Who Were Transferred or Admitted to the ICU Within 24 Hours of Hospital Arrival	Process	Facility
	Concept *(gap for measure development)*	Timely Molecular Assessment of Pathogen in Severe CAP	Process	Clinician / Facility
	Concept *(gap for measure development)*	Point-of-Care Testing for Pathogen Identification to Guide Same-Day Treatment	Process	Clinician / Facility
Treatment	Concept *(gap for measure development)*	Antibiotic Section, Dosing, and Duration of Treatment	Process	Clinician / Facility
	Concept *(gap for measure development)*	Timely De-Escalation of Antibiotic Therapy	Process	Clinician / Facility
Outcome	Existing *(gap in program measure sets)*	National Healthcare Safety Network (NHSN) Antimicrobial Use Measure	Outcome	Facility
	Concept *(gap for measure development)*	Frequency of Pathogen Identified	Outcome	Facility
	Concept *(gap for measure development)*	Frequency of Identified Multidrug Resistant Cases	Outcome	Facility
Resource Use	Existing *(gap in program measure sets)*	Hospital-Level Risk-Standardized Payment Associated with a 30-Day Episode of Care for Pneumonia	Outcome	Facility
Structural	Concept *(gap for measure development)*	Implementation of Prospective Antimicrobial Use Audit / Frequency of Review	Structural	Facility
	Concept *(gap for measure development)*	Implementation of Antibiotic Clinical Decision-Support (CDS) / Order Entry	Structural	Facility

Gaps in Program Measure Sets

As detailed in Table 6, Discern Health identified available measures relevant to the CAP treatment episode that are not currently used in VBP measure sets. These include:

- A process measure assessing whether vital sign information is captured for patients with CAP, an important process related to risk severity screening ("Vital Signs for Community-Acquired Bacterial Pneumonia").
- Process measures assessing administration of blood cultures in emergency room (ER) or inpatient cases. While these measures do not assess use of rapid diagnostics, blood cultures are one recommended tool for CAP diagnosis ("Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital" and "PN3a – Blood Cultures Performed Within 24 Hours Prior to or 24 Hours After Hospital Arrival for Patients Who Were Transferred or Admitted to the ICU Within 24 Hours of Hospital Arrival").
- An NHSN measure for determining antimicrobial use is an important outcome for utilization and adverse clinical events resulting from overuse of antibiotics in treating CAP. This measure is under consideration by CMS for inclusion in the HIQR program and may have broader utility in VBP ("National Healthcare Safety Network (NHSN) Antimicrobial Use Measure").
- A resource use measure for pneumonia episodes is valuable for driving appropriate use of antibiotics, as accurate diagnostic testing drives down overuse of unnecessary antibiotics. However, this measure should be considered carefully to ensure it does not incentivize underuse of appropriate but higher-cost diagnostics ("Hospital-Level Risk-Standardized Payment Associated with a 30-Day Episode of Care for Pneumonia").

Gaps for Measure Development

There are numerous gaps in available measures related to the use of diagnostic testing for CAP, as it relates to preventing AMR. Measure concepts that can fill these gaps, and which are detailed in Table 6, include:

- A process measure for severity screening in CAP, which is an important step in identifying patients who may be at risk for pathogen infections depending on clinical indications and seasonal risks ("Risk Severity Screening for Pneumonia Performed").
- Measures assessing use of diagnostic tests to differentiate pathogen type and inform short-term treatment selection:
    - A process measure assessing use of molecular testing (including PCR and other nucleic acid amplification technologies) to rapidly diagnose bacterial and viral pathogens ("Timely Molecular Assessment of Pathogen in Severe CAP").
    - A process measure to leverage point-of-care or near-patient testing to determine same-day treatment opportunities ("Point-of-Care Testing for Pathogen Identification to Guide Same-Day Treatment").

- A process measure to assess the selection, dosing, and duration of antibiotic treatment, particularly where broad and ineffective treatment should be terminated. This measure could indicate quality issues where the duration or count of days was longer than anticipated ("Selection, Dosing, and Duration of Antibiotic Treatment").
- A process measure concept assessing whether antibiotic therapy was de-escalated in a timely manner could also be useful in determining if inappropriate therapy resulted in a longer treatment period ("Timely De-Escalation of Antibiotic Therapy").
- Outcome measures assessing issues associated with poor diagnostic testing:
    - An outcome measure evaluating the frequency with which pathogens were identified would demonstrate how effectively hospitals are using diagnostic tests to drive targeted therapy ("Frequency of Pathogen Identified").
    - An outcome measure evaluating the frequency of identified multidrug resistant cases could inform the extent to which misuse of antibiotics is contributing to AMR ("Frequency of Identified Multidrug Resistant Cases").
- Structural measures to support existing activities promoting participation in antibiotic stewardship programs. These measures will help ensure standardization of stewardship program elements that drive appropriate use of antibiotic therapy and rapid diagnostics:
    - A structural measure to assess the use of prospective audits and reviews as part of stewardship programs ("Implementation of Prospective Antimicrobial Use Audit / Frequency of Review").
    - A structural measure supporting the implementation of clinical decision support (CDS) or order entry systems for antibiotic selection that direct physicians toward appropriate use based on clinical factors ("Implementation of Antibiotic Clinical Decision-Support (CDS) / Order Entry").

Hip and Knee Implants for Total Hip or Knee Arthroplasties

TYPE OF TECHNOLOGY
Implant Technology

THA/TKA PREVALENCE
>600,000 knee replacement and >300,000 hip replacement surgeries performed annually in the U.S.

Hip and knee implants are a type of orthopedic prosthesis used in joint replacement procedures. During prosthetic surgery, surgeons remove the damaged surfaces of hip or knee joints and replace them with artificial implants, which can improve motor functionality and reduce issues that affect quality of life, such as pain resulting from diseased cartilage and bone.

Hip and knee implants often include the same core components, but vary in terms of design and materials used. Implants may be made of metal, plastic, ceramic, or a mixture of materials but must be biocompatible to avoid a rejection response. They may be fixed to the bone using bone cement or they may be "press fit" so that bone grows around the implant itself. Selection of prosthetic implants in surgery can be based on multiple factors, including the patient's needs, anatomy, and general health; the surgeon's experience and familiarity with the device; and the cost and performance record of the implant.[51,52]

Total Hip or Knee Arthroplasty

Total hip or knee arthroplasty (THA or TKA) may be indicated if a patient is experiencing chronic joint pain or disability. Common causes of joint pain are osteoarthritis, rheumatoid arthritis, and post-traumatic arthritis following a serious injury. Surgery involves removing damaged bone and cartilage, resurfacing the bone, and implanting a prosthetic device. According to AHRQ, more than 600,000 knee replacements and 300,000 hip replacements are performed each year in the U.S.[51,53] As of 2010, there are approximately 7 million people in the U.S. living with a total hip or knee replacement (2.5 million THAs and 4.7 million TKAs).[54]

THA or TKA is one treatment option for patients with joint pain. Non-surgical treatment, including physical therapy, exercise, or medication such as NSAIDs or corticosteroids, is typically prescribed prior to a patient being referred for surgery.

Hip or Knee Implants for Total Hip or Knee Arthroplasty

Hip and knee implants are an integral component of THA/TKA surgery. However, clinical guidelines generally do not differentiate between selection of implantable devices, optimal product designs, or the surgical method as part of the treatment pathway. The American Academy of Orthopedic Surgeons (AAOS) recommends the following implantable devices:[55,56,57]

- Cemented femoral stems in hip implants recommended for use in patients undergoing arthroplasty for femoral neck fractures
- Cephalomedullary hip devices recommended for use in patients with stable or unstable intertrochanteric fractures, or subtrochanteric or reverse obliquity fractures
- Appropriate use criteria guidelines encourage shared decision-making between the patient and surgeon with an emphasis on realistic expectations

The AAOS guidelines do not make any recommendation between selection of cruciate retaining, polyethylene tibial, cemented or cementless femoral or tibial components, or

hybrid fixation knee implants. Other guidelines reviewed, including those developed by the American College of Rheumatology and the American Association of Hip and Knee Surgeons, either did not examine implant selection or surgical approach as a clinical topic or did not make practice recommendations.

These recommendations for implant selection were based on high- or moderate-quality evidence. Additional studies reviewed in the scope of Discern Health's analysis identified certain demonstrated benefits associated with implant selection. These benefits included lower revision rates for both hip and knee replacement, preservation of knee bone stock following replacement, avoidance of perioperative femoral hip fractures, and improving the overall implant-related failure rate through better performance and durability. "Demand matching" an implant to a patient's need based on factors such as age, activity level, life expectancy, and bone quality has been used as a cost containment strategy in some payment models. However, these approaches may not consider long-term outcomes and may not truly reflect a patient's preference for post-surgical functionality. AAOS criteria for recommending a specific procedure (TKA, unicompartmental knee arthroplasty, or realignment of osteotomy) depend upon a detailed review of the patient's pain, range of motion, functional instability, arthritic involvement, imaging, limb alignment, mechanical symptoms, and age.

Total Hip and Knee Arthroplasty Quality Landscape

Discern Health identified potential measurement opportunities within the THA/TKA care episode. These included opportunities around diagnosis and assessment (physical examinations, risk and functional assessments, and imaging); treatment (patient education, referrals for physical therapy, timely initiation of medical therapy or surgery, selection of surgery based on patient need); monitoring (imaging and referrals for physical therapy and rehabilitation); and outcomes (post-surgical complication rates, patient-reported change in function or quality of life and revision rates). The full list of measurement opportunities is detailed in Appendix D.

Through its measure scan, Discern Health identified over 35 quality measures that aligned with measurement opportunities, or THA/TKA surgery generally. Of these, 25 were determined to indirectly assess care processes and outcomes that impact or are impacted by selection of hip or knee implant.* The identified quality measures assess whether physicians conduct physical examinations, conduct functional assessments, or collect patient-reported functional data. The measures also assess whether physicians track outcomes associated with change in functional status or quality of life following surgery, short-term outcomes such as post-surgical readmissions, complications and reoperations, and mortality following hip replacement or fracture.

Many of the existing quality measures are used in VBP models relevant to THA/TKA procedures, such as the hospital and physician pay-for-reporting and pay-for-performance programs. Measures assessing the process of collecting functional data and interpreting change are available to report under MIPS. The HIQR and HVBP programs assess both THA/

* Excluded measures focused on general surgery practices such as antibiotic infusions or venous thromboembolic risk evaluations, or shared decision-making for medical therapy.

TKA complications and a general hospital patient experience measure. The HIQR and HRRP programs assess hospitals based on a 30-day THA/TKA hospital readmission measure. Notably, the CJR episode-payment demonstration model under CMMI includes a limited measure set (short-term post-surgical complications and hospital patient experience). While facilities in the model are incentivized to collect PRO functional status data, CMS does not yet assess performance based on changes in functional status or quality of life. Additional quality measures that assess rates of adverse surgical events (such as surgical site infection or deep vein thrombosis) and other safety outcomes were identified as part of VBP models. The full list of relevant quality measures and their use in VBP models is detailed in Appendix D.

Remaining Measure Gaps

Important gaps remain between the measurement opportunities identified and the available THA/TKA measures. Table 7 summarizes a list of available measures not used in Medicare VBP models, and measure concepts identified by Discern that, if used in VBP models, would guide appropriate care of patients receiving hip or knee implants through THA/TKA.

Table 7. THA/TKA Hip and Knee Implant Priority Measure Gaps

Domain	Availability	Title	Type	Level of Analysis
Diagnosis	Existing *(gap in program measure sets)*	Physical Examination	Process	Clinician
	Existing *(gap in program measure sets)*	Functional Status Assessment for Total Hip Replacement	Process	Clinician / Facility
	Existing *(gap in program measure sets)*	Functional Status Assessment for Total Knee Replacement	Process	Clinician / Facility
	Existing *(gap in program measure sets)*	Functional Outcome Assessment	Process	Clinician / Facility
Treatment	Concept *(gap for measure development)*	Appropriate Surgical Intervention Selected Based on Patient Criteria	Process	Clinician / Facility
	Existing *(gap in program measure sets)*	Identification of Implanted Prosthesis in Operative Report	Process	Clinician
	Concept	Shared Decision-Making in Implant Selection	PRO	Clinician / Facility
Monitoring	Concept *(gap for measure development)*	Use of Appropriate Imaging to Monitor Implant	Process	Clinician
	Concept *(gap for measure development)*	Timely Referrals for Post-Operative Physical Rehabilitation	Process	Clinician / Facility
Outcomes	Concept *(gap for measure development)*	Patient-Reported Change in Daily Living	PRO	Clinician / Facility
	Existing *(gap in program measure sets)*	Unplanned 30-Day Reoperation in Post-Operative Period	Outcome	Clinician / Facility
	Concept *(gap for measure development)*	Risk-Adjusted Multi-Year Revision Rate	Outcome	Clinician / Facility
	Concept *(gap for measure development)*	Implant Failure Rate	Outcome	Clinician / Facility

Gaps in Program Measure Sets

As detailed in Table 7, Discern Health identified available measures relevant to the THA/TKA care episode that are not currently used in VBP measure sets, or which are not being used comprehensively in relevant programs. These include:

- PRO Measures. Current VBP programs do not adequately assess patient outcomes linked to THA/TKA procedures. Discern Health identified gaps in the use of functional assessment and functional outcome measures within VBP models–currently, these measures are optional to report under MIPS but are not tied to payment in hospital models or the CJR. Optional reporting under MIPS is also a potential gap, particularly where CMS is otherwise assessing cost containment for hip and knee treatment episodes.
    - Discern Health identified functional status assessment process measures that should be incorporated into THA/TKA-focused models of care to ensure providers are collecting data used to assess functional or quality of life outcomes. Further, these models should ideally leverage PRO performance measures to determine whether patients were satisfied with function and quality of life as a result of surgery ("Functional Status Assessment for Total Hip Replacement," "Functional Status Assessment for Total Knee Replacement," and "Functional Outcome Assessment").
- A process measure to assess whether physical assessments occur prior to treatment, which can inform decision-making for surgery ("Physical Examination").
- A process measure to assess whether implanted prostheses are documented in operative reports, which can support appropriate tracking of selected prostheses ("Identification of Implanted Prosthesis in Operative Report").
- An outcome measure of short-term re-operation. This measure is optional for reporting in MIPS, but is not used in other hospital- or facility-based models. Unplanned re-operations are an adverse outcome, and could indicate inappropriate treatment ("Unplanned 30-Day Reoperation in Post-Operative Period").

Gaps for Measure Development

There are numerous gaps in available measures related to the use of hip and knee implants for total hip or knee replacement. Measure concepts that can fill these gaps, and which are detailed in Table 7, include:

- A PRO measure assessing whether shared decision-making between a patient and provider (reported by the patient) has occurred prior to surgery. Patients should be informed about both the procedure and the prosthetic, and the potential effects on functionality and quality of life, before undergoing surgery ("Shared Decision-Making in Implant Selection").
- A process measure assessing whether appropriate surgical interventions were selected based on pain, mobility, function, and other factors ("Appropriate Surgical Intervention Selected Based on Patient Criteria").

- Measures assessing monitoring or follow-up activities that could impact longer-term outcomes following surgery, and which are at risk under cost containment incentives.
    - A process measure assessing timely imaging to monitor implanted devices ("Use of Appropriate Imaging to Monitor Implant").
    - A process measure assessing whether patients are referred to physical therapy or rehabilitation following surgery ("Timely Referrals for Post-Operative Physical Rehabilitation").
- An outcome measure to assess multi-year revision rates ("Risk-Adjusted Multi-Year Revision Rate").
    - While VBP programs do use some short-term outcome measures, such as readmissions, complications, and re-operation rates, these time horizons are not sufficient to fully determine the adequacy and appropriateness of the implant or surgery. Discern Health noted that there is a gap in multi-year assessments of revision rates and implant failures. Policymakers must consider the application of such measures in population- or episode-based payment models to assess quality across performance periods.
- An outcome measure assessing a clinician or facility's implant failure rate. Similar to revision rates, this measure could be used to monitor the success of implant selection at facilities performing joint surgery ("Implant Failure Rate").
- A PRO measure assessing patient-reported change in daily living. Specifically, such a measure could look beyond existing functionality assessments to assess whether patients are able to forget about a joint as a result of a successful treatment.[58] This assessment could apply to patients receiving conservative therapy or surgical interventions, and would indicate whether a prosthesis is impeding the quality of a patient's life on a daily basis ("Patient-Reported Change in Daily Living").

Minimally Invasive Colectomy for Inflammatory Bowel Disease

TYPE OF TECHNOLOGY
Surgical and Recovery Tools

IBD PREVALENCE
1.3 million people in the U.S.

Minimally invasive surgery is a method that serves as an alternative to open surgery. Minimally invasive methods reduce the incision size and can help to improve post-surgical wound healing and reduce the risk of infection and pain, as compared to open surgery, which can result in operative trauma. Further, minimally invasive surgeries may take longer to perform, but can reduce the total time of hospitalization.

Minimally invasive techniques may be used for both diagnosis and treatment of colorectal diseases. Endoscopy, the use of a slender optical tube instrument, is useful in combination with biopsy for determining diagnoses in patients with colorectal conditions. Endoscopy can be particularly useful to surgeons in determining the type of surgical intervention needed, and is also important for cancer surveillance in this population.[59] Advanced endoscopic tools, such as narrow-band imaging, are also useful in assessing mucosal surface structures and small blood vessels to identify neoplastic lesions.[60,61]

Colectomies, or procedures in which all or part of the colon is removed (also called a bowel resection), may be performed as an open or minimally invasive surgery. The minimally invasive procedure itself, also called laparoscopic surgery, requires the surgeon to make several small incisions in the abdomen while a thin, fiber-optic lighted laparoscope (a type of endoscope) and specially designed surgical instruments are inserted to perform the surgery.[62] Laparoscopic colectomy may be enhanced by using electronic or robotic tools that help reduce the number of incisions and stabilize the surgical procedure. Advanced imaging technologies that improve laparoscopic procedures, along with energy devices that can cut and cauterize tissue quickly, can further support tissue dissection, manipulation, and identification of critical structures to avoid injury during the procedure.[63,64]

Inflammatory Bowel Disease (IBD) and Colectomy

Inflammatory bowel disease, or IBD, is a category of chronic conditions resulting in inflammation of the gastrointestinal tract. IBD includes two major types of disease: Crohn's disease (when inflammation affects the entire digestive tract) and ulcerative colitis (where only the large intestine is affected).[65] Approximately 1.3 million people in the U.S. suffer from IBD. Ulcerative colitis is more common in men, while Crohn's disease is more common in women.[66]

IBD cannot be cured with pharmaceuticals. Treatment depends on the type of IBD a patient presents with. Pharmaceutical therapies vary depending upon the severity of disease and patients' preferences. Steroids may be used to address symptoms, and biological therapies including tumor necrosis factor (TNF) inhibitors may be required to control severe or resistant disease. Surgery (including proctocolectomy) may cure ulcerative colitis. A colectomy will not cure Crohn's disease, but severe cases may warrant bowel resection.

Minimally Invasive Surgery for IBD Treatment

For patients with IBD who require a colectomy, minimally invasive procedures may be an option. Guidelines from the American Society of Colon and Rectal Surgeons (ASCRS) make the following recommendations:[67,68]

- Patients with Crohn's disease experiencing massive hemorrhage may be managed by interventional radiologic or endoscopic techniques
- Minimally invasive or open colectomy with end ileostomy is recommended for Crohn's disease or ulcerative colitis requiring emergency or urgent surgery
- Minimally invasive or open resection of affected bowel is recommended for Crohn's disease of jejunum, proximal ileum, terminal ileum, or ileocolon without short-bowel syndrome
- Open proctocolectomy with ileostomy is recommended for elective surgery in ulcerative colitis
- Patients with longstanding Crohn's disease or ulcerative colitis should undergo endoscopic surveillance

In general, guidelines recommend minimally invasive surgery as an equivalent option to open colectomy, except for elective proctocolectomy to cure ulcerative colitis. These recommendations are based on substantial evidence. In the studies Discern Health reviewed, many potential benefits for minimally invasive surgery were reported. These included utilization benefits (shorter hospital stay, higher discharge rate, lower cost), benefits related to recovery (rapid resolution of postoperative ileus (or postoperative bowel propulsion), lower rates of ostomy (or necessary artificial stomas), improved construction of subsequent pelvic pouches), quality of life benefits (reduced post-operative pain, improved pulmonary function, lower levels of inflammatory and stress response), as well as lower mortality and reduced incidence of complications or morbidity.

IBD Quality Landscape

Discern Health identified several measurement opportunities within the IBD care episode. These included opportunities for diagnosis (performing timely colonoscopy, assessing shared decision-making and counseling for treatment, performing risk assessments), treatment (timely initiation of steroid therapy, TNF inhibitors, or surgery), monitoring (colorectal cancer screening, timely provision of post-operative pharmacologic prophylaxis), outcomes (surgical mortality rate, complication rate following colectomy (such as surgical site infection or anastomotic leak), return of normal bowel function, hospital length of stay and readmissions), as well as structural measures (volume of minimally invasive colectomies performed). The full list of measurement opportunities is detailed in Appendix D.

Through its measure scan, Discern Health identified 16 quality measures impacting the IBD treatment pathway. 12 measures were determined to indirectly relate to the use of minimally invasive surgery.* The identified quality measures include a process measure to document the type, anatomic location, and activity of IBD, which is an important process in ensuring diagnosis informs treatment selection, and several outcome measures for colon surgery generally (surgical site infection, gastrointestinal hemorrhage rate, mortality and unplanned reoperation, and other morbidities).

* Excluded measures included those that address use of colonoscopy, colorectal cancer screening, or use of medical therapy to treat IBD.

Certain IBD measures, including those assessing timely use of medical therapy, are in physician program use through MIPS; however, this does not include the identified quality measure to document IBD type, anatomic location, and activity. Outcome measures for colon surgery are used in hospital VBP programs, including the HAC-R, HIQR, HOQR, and HVBP programs. Most notably, the HIQR, HVBP, and HAC-R programs incorporate the American College of Surgeons' (ACS's) and CDC's surgical site infection measure, which assesses 30-day infection rates following abdominal surgeries including colectomy. The HOQR program assesses unplanned hospital visits following outpatient surgery. The full list of relevant quality measures and their use in VBP models is detailed in Appendix D.

Remaining Measure Gaps

Gaps remain between the measurement opportunities identified and the available measures. Table 8 summarizes a list of available measures not used in Medicare VBP models, and measure concepts identified by Discern that, if used in VBP models, would guide appropriate care of patients with IBD, including use of minimally invasive surgery.

Table 8. IBD Minimally Invasive Colectomy Priority Measure Gaps

Domain	Availability	Title	Type	Level of Analysis
Diagnosis	Existing *(gap in program measure sets)*	Inflammatory Bowel Disease (IBD): Type, Anatomic Location, and Activity	Process	Clinician
	Concept *(gap for measure development)*	Risk Assessment Performed	Process	Clinician / Facility
Treatment	Concept *(gap for measure development)*	Timely Initiation of Colectomy	Process	Facility
Outcome	Existing *(gap in program measure sets)*	Risk Adjusted Colon Surgery Outcome Measure	Outcome	Facility
	Existing *(gap in program measure sets)*	Gastrointestinal Hemorrhage Mortality Rate	Outcome	Facility
	Concept *(gap for measure development)*	Anastomotic Leak Rate	Outcome	Facility
	Concept *(gap for measure development)*	Patient-Reported Change in Quality of Life Following Colectomy	Outcome	Clinician / Facility
Structural	Concept *(gap for measure development)*	Monitoring Volume of MIS Colectomy at Facility	Structural	Facility

Gaps in Program Measure Sets

As detailed in Table 8, Discern Health identified available measures relevant to the IBD treatment episode that are not currently used in VBP measure sets. These include:

- A process measure to assess the type, anatomic location, and activity level for IBD. Documentation of these factors is an important initial step in ensuring the right patients with IBD who are candidates for surgery are not overlooked ("Inflammatory Bowel Disease (IBD): Type, Anatomic Location, and Activity").

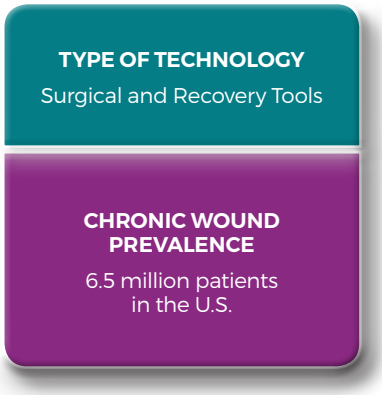
- A risk-adjusted measure assessing colon surgery outcomes. The adverse surgical outcomes assessed include cardiac arrest, hospital-acquired pneumonia, and septic shock among others. Minimally invasive procedures may prove beneficial when considering these outcomes as compared to open procedures ("Risk Adjusted Colon Surgery Outcome Measure").
- An AHRQ inpatient outcome measure for gastrointestinal hemorrhage, which is an important indicator of death due to intestinal bleeding that may be impacted by selection of minimally invasive procedures ("Gastrointestinal Hemorrhage Mortality Rate").

Gaps for Measure Development

There are numerous gaps in available measures related to the use of minimally invasive surgical tools in IBD management. Measure concepts that can fill these gaps, and which are detailed in Table 8, include:

- A process measure promoting risk assessment for patients with IBD, including risk assessment prior to an emergent or elective surgical intervention. Performing risk assessments, which may include C-reactive protein testing, reviewing disease location, or assessing the presence of perianal disease, may be helpful in predicting disease progression and avoiding certain complications during surgery ("Risk Assessment Performed").[69,70]
- A process measure assessing timely initiation of colectomy and selection of surgical intervention (minimally invasive or open procedures). Existing IBD measures are focused solely on medical therapy interventions, and do not address performance gaps related to surgery ("Timely Initiation of Colectomy").
- An outcome measure assessing anastomotic leak rates, a dangerous complication of surgery that can potentially be avoided through use of endoscopic visualization ("Anastomotic Leak Rate").[71,72]
- A patient-reported outcome measure assessing important post-surgical outcomes, including pain, return to normal bowel function, or quality of life, which may incorporate issues such as retention of sexual function or other factors. Numerous PRO tools for colorectal surgery have been developed, and may be leveraged for development of a performance measure ("Patient-Reported Change in Quality-of-Life Following Colectomy").[73]
- Finally, in payment environments where cost containment may be a factor, structural assessments of the volume of minimally invasive procedures performed at a facility may be necessary to ensure facilities are not underutilizing minimally invasive procedures ("Monitoring Volume of MIS Colectomy at Facility").

Negative Pressure Wound Therapy for Chronic Wound Care



Negative Pressure Wound Therapy (NPWT) is a type of dressing used to treat acute or chronic wounds that are expected to have difficulty healing. The use of NPWT is intended to accelerate wound healing by improving the formation of new blood vessels and blood flow, and reducing risks such as edema or inflammation.[74]

NPWT uses a vacuum to apply sub-atmospheric pressure to a wound through a sealed dressing, generally made of polyurethane. Prior to application, the wound is packed with a sterile foam or gauze dressing to ensure blood clots or tissue are not pulled into the vacuum. The dressing is covered with a polyurethane drape to protect against infection and create a seal. The physician determines the strength of suction, between -125 and -75 mmHg depending on the wound, the patient's tolerance, and the amount of time the vacuum is applied.[75]

Chronic Wound Care

Chronic wounds do not heal in a predictable timeframe as other types of acute wounds, such as surgical wounds, do. Chronic wounds, or "ulcers," may be classified into three categories: (1) venous and arterial ulcers, occurring in the legs and accounting for 70%-90% of all chronic wounds;[76] (2) diabetic ulcers, occurring in patients with diabetic neuropathy; and (3) pressure ulcers, occurring in patients who are paralyzed or have limited movement.[77] Globally, there are approximately 9.7 million venous ulcers, 10 million diabetic ulcers, and 4.5 million pressure ulcers. In the U.S, about 6.5 million persons are affected by chronic wounds.[78] As the population ages, the growth rate of chronic wounds has correspondingly increased. The annual growth rate for pressure and venous ulcers diagnoses is 6%-7%. The annual growth rate for diabetic ulcer diagnoses is 9%, which corresponds to the increasing prevalence of Type 1 Diabetes.[79]

Treatment of chronic wounds most commonly includes proper care through frequent dressing changes and ensuring that the wound is kept clean. Antibiotics may be required to prevent infection, and anti-inflammatory medications may be necessary. For some patients, physicians may use surgical debridement to remove accumulated dead tissue. Other adjunctive treatments may or may not be appropriate for certain types of wounds. Adjunctive treatments include ultrasound, lasers, ultraviolet light, superficial heating, electrical stimulation, and NPWT.[80]

NPWT for Chronic Wound Care Treatment

NPWT is indicated for certain types of ulcers. For other ulcers, guidelines indicate that more research and evidence is needed. Guideline recommendations are based on mixed-quality evidence. Professional organizations, such as the Wound Healing Society (WHS); Wound, Ostomy and Continence Nurses Society (WOCN);[81,82,83] and Society for Vascular Surgery (SVS),[84] provide recommendations for the use of NPWT in chronic wound care:

- Recommended for chronic or nonhealing diabetic foot ulcers
- Recommended for stage III or IV pressure ulcers
- No recommendation for venous or arterial ulcers

- WOCN recommends NPWT for lower extremity arterial disease wounds with infected vascular grafts

Discern Health's scan of the available literature identified potential benefits of NPWT, including reduced time to healing following diabetic foot amputation and for leg ulcers; a higher percentage of healed wounds following diabetic foot amputation, in treatment of diabetic foot ulcers generally, and for patients with acute and chronic wounds generally; reduced wound bed preparation time and increased amount of granulation tissue, as well as decreased wound size and depth for chronic leg wounds; higher uptake of skin grafts and reduction in the number of re-amputations following diabetic foot amputation; and reduction in infection risk and in the number of dressing changes.

Chronic Wound Care Quality Landscape

Discern Health identified several measurement opportunities within the chronic wound care episode. These include opportunities related to diagnosis (risk screening, collection of patient history, nutritional screening, referrals to wound specialists), treatment (timely debridement, dressing selection, timely revascularization, selection of adjunctive treatment), monitoring (smoking cessation counseling, implementation of exercise programs, foot examinations, assessment of bacterial burden, or the level of bacteria in the wound potentially contributing to inflammation), and outcomes (wound infection and amputation rates, patient-reported change in depth or size of the wound, pain). The full list of measurement opportunities is detailed in Appendix D.

Through its measure scan, Discern Health identified over 50 measures that related directly or indirectly to the chronic wound care pathway. Among these, 20 measures indirectly assess care processes and outcomes that impact or are impacted by NPWT.* The identified quality measures assess rates or prevalence of pressure ulcers, or the status of pressure ulcers that may be new or worsened. Other measures assess the status of surgical wounds and the rate of lower-extremity amputations among patients with diabetes. Measures developed by the U.S. Wound Registry (USWR) assess processes and outcomes for diabetic foot and venous leg ulcers.

Because chronic wound care treatment most often occurs in post-acute care settings, such as nursing homes, long-term care hospitals, or home health services, Discern Health's review of VBP models focused on the NHQI, LTCHQR, and HHQR and HHVBP programs. Nursing home and home health quality data reported to CMS come from resident and patient assessment data routinely collected at specified intervals during a patient's time in care. The instruments, called the Minimum Data Set (MDS – Nursing Homes) and Outcome and Assessment Information Set (OASIS – Home Health), allow for reporting of the survey based quality measures used in the programs. These programs use many of the identified measures as part of their quality assessment. Other VBP models, such as the Medicare ACO models, do not assess wound care prevention or treatment. The full list of relevant quality measures and their use in VBP models is detailed in Appendix D.

* Certain measures identified in the scan, such as smoking cessation counseling and foot exams for patients with diabetes, or processes and outcomes associated with hyperbaric oxygen therapy, are important for chronic wound care, but were not directly or indirectly relevant to the use of NPWT.

Remaining Measure Gaps

Many gaps remain between the measurement opportunities identified and the available chronic wound care measures. Table 9 below summarizes available measures not used in Medicare VBP models, and measure concepts identified by Discern that, if used in VBP models, would guide appropriate chronic wound care, including appropriate use of NPWT.

Table 9. Chronic Wound Care NPWT Priority Measure Gaps

Domain	Availability	Title	Type	Level of Analysis
Diagnosis	Concept *(gap for measure development)*	Risk Screening Used in Care Planning Discussions	Process	Clinician
	Existing *(gap in program measure sets)*	Patient Reported Experience of Care: Wound Related Quality of Life [Data Collection Measure]	Process	Clinician / Facility
	Existing *(gap in program measure sets)*	Patient Reported Experience of Care: Wound Outcome [Data Collection Measure]	Process	Clinician / Facility
Treatment	Existing *(gap in program measure sets)*	Nutritional Screening and Intervention Plan in Patients with Chronic Wounds and Ulcers	Process	Clinician / Facility
	Existing *(gap in program measure sets)*	Plan of Care Creation for Diabetic Foot Ulcer (DFU) Patients not Achieving 30% Closure at 4 Weeks	Process	Clinician / Facility
	Concept *(gap for measure development)*	Timely Use of NPWT	Process	Clinician
Monitoring	Concept *(gap for measure development)*	Bacterial Burden Assessed	Process	Clinician
	Concept *(gap for measure development)*	Patient Compliance with Adjunctive Wound Therapies Assessed	Process	Clinician
Outcomes	Concept *(gap for measure development)*	Chronic Wound Infection Rate	Outcome	Clinician / Facility
	Concept *(gap for measure development)*	Patient Reported Change in Chronic Wound Status	PRO	Clinician / Facility
	Existing *(gap in program measure sets)*	Diabetic Foot Ulcer (DFU) Healing or Closure	Outcome	Clinician / Facility
	Existing *(gap in program measure sets)*	Lower-Extremity Amputation Among Patients with Diabetes	Outcome	Clinician / Facility
	Concept *(gap for measure development)*	Re-Amputation Among Patients with Diabetes	Outcome	Facility

Gaps in Program Measure Sets

Currently available wound care measures in use by CMS focus on prevalence and status of pressure ulcers, wounds that can acutely affect patients with limited mobility in a post-acute hospital setting. As detailed in Table 9, Discern Health identified available measures relevant to the chronic wound care episode for other types of ulcers. These include:

- USWR-developed measures that focus on processes and outcomes related to diabetic foot ulcer care. Appropriate use of NPWT should be included in treatment plans for patients with non-healing wounds, and its use can potentially impact healing and prevent amputation:
    - A process measure assessing whether plans of care are developed for patients whose wounds have not healed ("Plan of Care Creation for Diabetic Foot Ulcer (DFU) Patients not Achieving 30% Closure at 4 Weeks").
    - An outcome measure assessing healing or closure for diabetic foot ulcers ("Diabetic Foot Ulcer (DFU) Healing or Closure").
    - An outcome measure assessing lower-extremity amputation rates ("Lower-Extremity Amputation Among Patients with Diabetes").
- USWR has also developed more generally applicable chronic wound care measures that are relevant to wound healing and the use of NPWT:
    - A process measure assessing screening and intervention of nutritional supplementation (malnutrition is known to be an adverse indicator for wound healing) ("Nutritional Screening and Intervention Plan in Patients with Chronic Wounds and Ulcers").
    - Process measures to collect patient-reported data about quality of life and wound outcomes relevant to healing ("Patient Reported Experience of Care: Wound Related Quality of Life" and "Patient Reported Experience of Care: Wound Outcome").

Gaps for Measure Development

There are several gaps in available measures related to the use of NPWT for chronic wound care. Measure concepts that can fill these gaps, and which are detailed in Table 9, include:

- A process measure to promote the use of risk screening results in care planning discussions. This chronic wound screening process can help ensure that patients with non-healing wounds are considered for appropriate wound dressings and therapies, such as NPWT, and the risk determinations inform shared decision-making ("Risk Screening Used in Care Planning Discussions").
- A process measure assessing appropriate use of NPWT. While NPWT is not appropriate for all patients, it is indicated for certain diabetic foot ulcers and non-healing pressure ulcers—there is a gap in process-related measures for appropriate initiation of NPWT in these populations ("Appropriate and Timely Use of NPWT").

- A process measure for monitoring how effectively patients are adhering to the use of adjunctive wound care therapies, including NPWT. Patient compliance should be assessed by physicians to ensure effective wound healing ("Patient Compliance with Adjunctive Wound Therapies Assessed").
- A process measure for monitoring of wounds' bacterial burden. This bacterial burden can lead to infection if untreated ("Bacterial Burden Assessed").
- An outcome measure assessing infection rates for chronic wounds. While there are measures assessing surgical site infection rates, there are not measures to assess infection rates in chronic wounds, which can be avoided through appropriate use of adjunctive therapies such as NPWT ("Chronic Wound Infection Rate").
- An outcome measure assessing patient-reported change in wound healing. While the USWR has developed PRO data collection tools, these tools have not yet been leveraged into a PRO performance measure, which could provide valuable patient-reported insight into wound status, healing (including changes in wound size and appearance) or failure to progress to an acceptable degree, and patient quality of life (including mobility, functionality, and pain) ("Patient Reported Change in Chronic Wound Status").
- An outcome measure assessing re-amputation of extremities affected by chronic wounds, particularly in patients with diabetic foot ulcers ("Re-Amputation Among Patients with Diabetes").

Prothrombin Time International Normalized Ratio Home Testing for Pulmonary Embolism

TYPE OF TECHNOLOGY
Durable Medical Equipment

PULMONARY EMBOLISM PREVALENCE
Third most common cause of death in hospitalized patients, with approximately 600,000 cases annually

Prothrombin time (PT) is a type of test that is used to measure how quickly a patient's blood will clot. This test can be used to diagnose cause of bleeding or blood clotting, and can also be used to monitor patients being treated with blood thinning medications (vitamin K antagonist therapy or anticoagulants), such as warfarin. PT test readings vary depending on the method used, and are adjusted to the "INR" or International Normalized Ratio. The INR is the ratio of a patient's PT to a control sample raised to a certain International Sensitivity Index depending on the test. A higher INR value indicates that the blood is clotting more slowly. For a patient on warfarin, an INR target range may be between 2.0 and 4.0, while for a healthy patient, an INR of 1.1 or below is considered normal.[85,86]

A home-based point-of-care PT test may be used by patients to monitor their own INR. Using the test, a patient draws a drop of blood via an automated and nearly painless finger prick. The drop of blood is placed on a test strip that is applied to a handheld monitoring device, which then displays the patient's INR. Home-based PT INR testing may be preferable to outpatient lab testing if it allows for faster testing to improve anticoagulant control.

Pulmonary Embolism (PE) and Anticoagulation

Pulmonary embolism is a condition where a substance, such as blood clots (thrombus), gas, or foreign objects, travels through the bloodstream and blocks arteries in the lung. PE may be caused by blood clots that travel to the lung, often from the leg, resulting in shortness of breath, chest pain, low blood pressure, and sudden death. Pulmonary embolism occurs in about 1 per 1,000 patients per year in the U.S., and is the third most common cause of death in hospitalized patients, with about 650,000 cases occurring annually.[87]

Patients who are at risk for PE or who are suspected of having PE usually are prescribed an anticoagulant, such as warfarin, that will reduce the risk of a clot. Newly developed direct oral anticoagulants (DOACs) offer an alternative to warfarin that has safety advantages and requires less monitoring. Patients may also receive thrombolytic therapy, intended to break up the blood clot.[88] Surgical approaches, including embolectomy or placement of vena cava filters, may also be an option.[89]

Prothrombin International Normalized Ratio Home Testing for Pulmonary Embolism Treatment

Home testing is one method for monitoring anticoagulant therapy for patients on warfarin who may be at risk for PE. Clinical guidelines around anticoagulant management, including those published by the American College of Chest Physicians (ACCP) and the American Academy of Family Physicians (AAFP), recommend the use of self-monitoring of INR:

- The ACCP recommends patient self-management, including the use of self-testing equipment, in place of usual outpatient INR monitoring

- The AAFP recommends point-of-care monitors be used in home settings for some patients on warfarin to monitor their INR

The Anticoagulation Forum recommends either clinical laboratory testing or point-of-care testing for patients on warfarin, as both approaches have been validated.[90] Clinical recommendations are based on moderate- to high-quality evidence that shows self-testing results in decreased mortality, enhanced INR control (measured as time in therapeutic range), decreased thromboembolic events, and improvement in patient satisfaction and quality of life. These benefits were shown without an increase in bleeding complications, an important safety concern for anticoagulation monitoring. However, to the extent that warfarin use remains in clinical practice, measures of PT INR testing, and point-of-care testing in particular, are an important element of value-based care.

Pulmonary Embolism Quality Landscape

Discern Health identified several potential quality measure opportunities within the PE care episode. These included diagnosis opportunities (risk scoring and timely assessments for patients at risk for PE, initiation of timely testing, such as imaging), treatment (timely initiation of warfarin therapy, thrombolysis therapy, and surgical interventions including vena cava filters), monitoring (timely initiation of supportive therapy, prescribing of INR self-testing), outcomes (post-treatment complication rates such as bleeding or thromboembolic events, mortality rate, and intermediate outcomes such as time in therapeutic range—a measure summarizing INR control over time), and practice structure opportunities (collection of patient-reported data, validating INR results between testing tools). The full list of measurement opportunities is detailed in Appendix D.

Through a comprehensive measure scan, Discern Health identified over 30 quality measures that applied to the PE treatment trajectory. 12 measures relate directly to INR testing or outcomes relevant to INR testing. The identified quality measures specifically promote INR monitoring for individuals receiving warfarin, but do not differentiate between outpatient laboratory testing and home monitoring. One intermediate outcome measure for therapeutic time in range, stewarded by the U.S. Department of Veterans Affairs, was identified. Other important outcome measures for hospital or post-surgical outcomes assess complication rates that include PE. Finally, Discern Health examined practice Improvement Activities that are included in the CMS MIPS physician payment program. Two activities specifically require physicians to attest to systematic anticoagulant monitoring or safety protocols, but do not include any requirements for home monitoring.

Few of the identified relevant measures are in program use. Two safety and surgical mortality measures developed by AHRQ (the PSI90 and PSI4 indicators) are in use in hospital performance programs including the HIQR, HVBP, and HAC-R programs. The identified process and outcome measures promoting use of INR monitoring and intermediate outcomes for INR monitoring are not currently in VBP program use. The full list of relevant quality measures and their use in VBP models is included in Appendix D.

Remaining Measure Gaps

Certain gaps remain between the measurement opportunities identified and the available PE quality measures. Table 10 summarizes a list of available measures not used in Medicare VBP models, and measure concepts identified by Discern that, if used in VBP models, would guide appropriate care of patients at risk for PE, including use of PT INR home testing for patients on warfarin.

Table 10. Pulmonary Embolism PT INR Home Testing Priority Measure Gaps

Domain	Availability	Title	Type	Level of Analysis
Monitoring	Existing *(gap in program measure sets)*	INR Monitoring for Individuals on Warfarin	Process	Clinician / Health Plan / Population
	Existing *(gap in program measure sets)*	INR Monitoring for Individuals on Warfarin after Hospital Discharge	Process	Facility
	Existing *(gap in program measure sets)*	Percentage of Hospitalized Patients on Warfarin for Whom Current International Normalized Ratio is Used to Monitor and Adjust Therapy	Process	Facility
	Concept *(gap for measure development)*	Home PT INR Testing Prescribed for Self-Management	Process	Clinician / Facility
Outcomes	Existing *(gap in program measure sets)*	Percent of Time in Therapeutic INR Range (TTR): Mean TTR Achieved Among Patients Who Received Prescriptions for Warfarin and Had Sufficient INR Values to Calculate TTR	Outcome	Facility
	Concept *(gap for measure development)*	Percentage of Critical INR Values	Outcome	Clinician / Facility
	Concept *(gap for measure development)*	INR Variability (Percentage of INRs Within Range)	Outcome	Clinician / Facility
	Concept *(gap for measure development)*	Acute Thromboembolic Event Rate	Outcome	Facility
	Concept *(gap for measure development)*	Rate of Emergency Room or Inpatient Admissions for Bleeding Events	Outcome	Facility
Structural	Concept *(gap for measure development)*	Use of Certified EHR to Collect Device-Reported Data	Structural	Clinician / Facility
	Concept *(gap for measure development)*	Comparison of Lab and Home Device Values	Structural	Clinician / Facility

Gaps in Program Measure Sets

As detailed in Table 10, Discern Health identified measures relevant to the PE treatment episode that are not currently used in VBP measure sets. These include:

- Process measures that promote INR monitoring for individuals on warfarin, and which could help ensure that consistent monitoring occurs under VBP models. These measures would help drive therapy adjustment to avoid costly adverse complications resulting in hospitalizations or death ("INR Monitoring for Individuals on Warfarin," "INR Monitoring for Individuals on Warfarin after Hospital Discharge," and "Percentage of Hospitalized Patients on Warfarin for Whom Current International Normalized Ratio is Used to Monitor and Adjust Therapy").
- An intermediate outcome measure that promotes tracking INR time in range. Consistent time out of range for target INR could lead to poor health status. ("Percent of Time in Therapeutic INR Range (TTR): Mean TTR Achieved Among Patients Who Received Prescriptions for Warfarin and Had Sufficient INR Values to Calculate TTR").

Gaps for Measure Development

There are numerous gaps in available measures related to the use of PT INR home testing kits. Measure concepts that can fill these gaps, and which are detailed in Table 10, include:

- A process measure to assess prescribing of home INR testing to competent and motivated patients. This measure could be specified for high-risk patients who need to test more frequently than other patients ("Home PT INR Testing Prescribed for Self-Management").
- Intermediate outcome measures to complement TTR measures.
    - Specifically, the utility of an existing TTR measure should be examined along with additional concepts, both for rates of "critical" INR results in a physician's panel (those values that represent a high bleeding risk), as well as for INR variability—the percentage of INR results that deviated from the patient's target ("Percentage of Critical INR Values" and "INR Variability (Percentage of INRs Within Range)").
- Outcome measures assessing adverse events associated with poor management of anticoagulants. While PE is a complication included in certain measures, these measures often assess peri-operative or immediate post-surgical care, while admission-level rates of thromboembolic events or major or minor bleeding events are not currently measured ("Acute Thromboembolic Event Rate" and "Rate of Emergency Room or Inpatient Admissions for Bleeding Events").
- Structural measures to assess the utilization and quality of device-reported data.

- Structural measures to compare and validate INR results. While the INR system is intended to standardize PT measurement, different variables including the sensitivity of the assay, its calibration and instrument effects, as well as post-analytic calculation can lead to discrepancies in INR interpretation between laboratory results and point-of-care testing. As such, providers who monitor patients using both home testing and laboratory methods should adhere to systems that compare and standardize results to avoid inaccuracies and misinterpretation of INR that can result in serious health consequences. These systems may involve verification protocols for PT/INR values that are unexpected past a defined threshold ("Implement Comparison of Lab and Home Device Values").[91]
- Structural measures to assess the collection and use of device-reported data in practice. PT INR home testing devices allow for patient-specific data to be reported to physicians, and the collection and use of this data in treatment planning should be considered for structural measurement—are providers using device-reported data to guide therapy? Is device-reported data being compared and standardized against laboratory-reported values? These questions are essential in avoiding potential negative consequences of misaligned test results ("Use of Certified EHR to Collect Device-Reported Data").

Stereotactic Body Radiation Therapy for Non-Small Cell Lung Cancer

TYPE OF TECHNOLOGY
Capital Equipment

LUNG CANCER PREVALENCE
Accounts for 14% of all cancers and 1 in 4 cancer-related deaths. Radiation therapy is used as a treatment for over 60% of patients.

Stereotactic radiation therapy (RT) is a form of external radiation therapy that uses special equipment to precisely deliver radiation to a tumor.[92] Stereotactic RT uses image guidance combined with precision delivery technology that allows physicians to give a greater combined dose of radiation over the course of fewer treatments when compared to conventional RT, which may require daily treatments over the course of several weeks.[93]

Stereotactic body radiation therapy (SBRT) (sometimes called stereotactic ablative radiotherapy, or SABR) refers to the use of stereotactic RT to treat tumors outside of the central nervous system.[94] SBRT uses four-dimensional diagnostic imaging to locate tumors and map the treatment area. Because tumors and organs throughout the body can move as the patient breathes, SBRT treatments require greater precision to ensure safe exposure to higher radiation doses.[93]

Lung Cancer and Radiation Therapy

Lung cancer is the leading cause of cancer deaths in the U.S., accounting for 1 in 4 cancer-related deaths and 14% of all cancers. Non-small cell lung cancer (NSCLC) is the most common type of lung cancer and may affect cells in the outer parts of the lung, squamous cells lining the inside of airways, or "large cells" that may appear in any part of the lung.[95] Radiation therapy is needed in over 60% of patients with lung cancer at least once during treatment.[96]

Radiation therapy is one treatment option for patients with certain stages of NSCLC, and may be the primary option for treatment or used as an adjuvant or neo-adjuvant treatment with chemotherapy or surgery. Computed tomography planned three dimensional conformal RT is considered to be the minimum standard in RT. Advanced technologies, including SBRT/SABR, are available for patients who cannot receive surgery.

Stereotactic Body Radiation Therapy for Non-Small Cell Lung Cancer (NSCLC) Treatment

SBRT/SABR is clinically indicated as an early stage intervention for certain patients with NSCLC. The National Comprehensive Cancer Network (NCCN) Guidelines® recommend SBRT for:[97]

- Patients who are medically inoperable or who refuse to have surgery after thoracic surgery evaluation
- Patients with high surgical risk (able to tolerate sublobar resection but not lobectomy (e.g., >75 years), poor lung function)

Guidelines developed by the American Society of Clinical Oncology (ASCO) and the American Society for Radiation Oncology (ASTRO) for definitive and adjuvant radiotherapy in locally advanced NSCLC make similar recommendations.[98] NCCN's recommendations are based on clinical evidence indicating that SBRT/SABR improves local tumor control and disease progression, limits toxicity, and improves survival.[94] Additional studies of SBRT's benefits

found that patients receiving SBRT experienced fewer severe adverse events and had lower treatment-related deaths compared to other modalities of treatment, and they experienced significantly less treatment regret compared to other forms of conventional radiation.[99,100]

NSCLC Quality Landscape

Discern Health identified numerous potential opportunities to measure processes, outcomes, and practice structures within the NSCLC care episode. These included measurement opportunities relevant to diagnosis of NSCLC (imaging and biopsy, cancer staging, referrals for oncology care teams including radiologists), structure (requiring multidisciplinary care team assessments in practice), treatment (timely initiation of surgery, definitive RT, or chemoradiation, safe levels of radiation dosing), monitoring (timely imaging, assessing smoking status, conducting patient experience surveys), and outcomes (patient survival, disease recurrence, and quality of life). The full list of measurement opportunities is detailed in Appendix D.

Through its measure scan, Discern Health identified over 30 quality measures that aligned with these measurement opportunities, including the use of radiation therapy for cancer treatment generally. 12 measures were determined to indirectly assess care processes and outcomes that impact or are impacted by use of radiation therapy, including SBRT.* The identified quality measures assess elements of diagnosis and assessment, such as staging and excision of lymph nodes for testing; safety, including radiation dosing limits; selection of care, including avoiding surgery for certain NSCLC cancer patients; monitoring, including quantifying pain intensity; and outcomes, including utilization of inpatient and outpatient facilities following a cancer care episode.

Few of the identified measures relevant to the NSCLC care trajectory are currently used in the representative Medicare value-based delivery and payment models reviewed. A limited number of lung cancer-specific measures are available for physician reporting under MIPS. Other models, including the OCM episode payment model and PCHQR for cancer hospitals, include general oncology measures, such as pain reporting or utilization-based outcome measures, but do not include any measures directly assessing care for patients with lung cancer. The full list of relevant quality measures and their use in VBP models is detailed in Appendix D.

Remaining Measure Gaps

Discern Health noted important gaps between the defined measurement opportunities and the available quality measures identified in its scan. Additional gaps exist between available quality measures and their use in Medicare value-based delivery and payment models. Table 11 summarizes a list of available measures not used in Medicare VBP models, and measure concepts identified by Discern that, if used in VBP models, would guide appropriate care of patients with NSCLC, including appropriate use of SBRT.

* Excluded measures assessed care processes and outcomes relevant to the NSCLC trajectory, such as mortality following surgery, but which were unrelated to the appropriate use of SBRT.

Table 11. NSCLC SBRT Priority Measure Gaps

Domain	Availability	Title	Type	Level of Analysis
Diagnosis	Existing *(gap in program measure sets)*	Pathology: Percentage of Pathology Reports for Primary Lung Carcinoma Resection Specimens that Include the pT Category, pN Category, and for NSCLC, Histologic Type	Process	Clinician
	Concept *(gap for measure development)*	Early Stage NSCLC Patients Referred to Radiation Oncologist	Process	Facility / Health Plan
Treatment	Concept *(gap for measure development)*	Medically Inoperable Patients (Stage I-II T1-3, N0, M0, or High-Risk Refusing Surgery) Receiving SABR/SBRT	Process	Clinician
	Concept *(gap for measure development)*	Appropriate RT Dosing for Patients Receiving SABR/SBRT	Process	Clinician
	Existing *(gap in program measure sets)*	Surgery Is Not the First Course of Treatment for cN2, M0 Lung Cases	Process	Clinician
Outcome	Concept *(gap for measure development)*	Risk-Adjusted NSCLC Recurrence Rate	Outcome	Facility
	Concept *(gap for measure development)*	Risk-Adjusted NSCLC Survival Rate	Outcome	Facility
	Concept *(gap for measure development)*	Patient Satisfaction with Shared Decision-Making regarding Access to Radiation Oncologists	Patient-Reported Outcome (PRO)	Facility / Health Plan
Structural	Concept *(gap for measure development)*	Use of Multidisciplinary Team in Early Stage NSCLC Evaluation	Structural	Facility / Health Plan

Gaps in Program Measure Sets

As detailed in Table 11, Discern Health identified available measures relevant to the NSCLC care episode that are not currently included in VBP measure sets. These include:

- A pathology reporting measure that assesses whether pathology reports include tumor-specific information. This information is necessary to ensure patients are directed toward appropriate therapy (including RT) ("Pathology: Percentage of Pathology Reports for Primary Lung Carcinoma Resection Specimens that Include the pT Category, pN Category, and for NSCLC, Histologic type").
- An American College of Surgeons measure that assesses whether non-surgical interventions (including RT) were the first choice in certain cases of cancer ("Surgery Is Not the First Course of Treatment for cN2, M0 Lung Cases").*

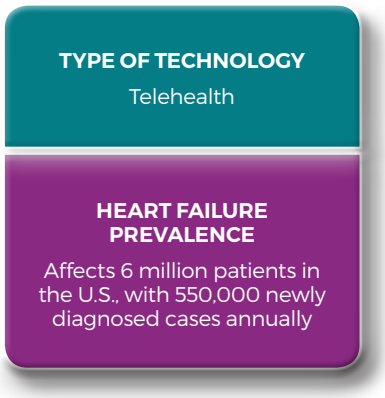
*This ACS measure is included in the Commission on Cancer quality accreditation program.

Gaps for Measure Development

There are many gaps in available measures related to the use of SBRT to treat NSCLC. Measure concepts that can fill these gaps, and which are detailed in Table 11, include:

- A process measure assessing referral rates of early stage NSCLC patients to radiation oncologists, which would evaluate access-related issues for patients in primary care or community settings ("Early Stage NSCLC Patients Referred to Radiation Oncologist")
    - Similarly, a PRO-PM or patient experience measure assessing patient satisfaction with shared decision-making and access to radiation oncologists would provide direct insight into whether patients experience access issues ("Patient Satisfaction with Shared Decision-Making and Access to Radiation Oncologists").
- A process measure assessing the use of SBRT as indicated for medically inoperable NSCLC patient populations ("Medically Inoperable Patients (Stage I-II T1-3, N0, M0, or High-Risk Refusing Surgery) Receiving SABR/SBRT").
- A process measure assessing whether SBRT was delivered to high-risk patients within safe radiation limits, a potential patient safety issue ("Appropriate RT Dosing for Patients Receiving SABR/SBRT").
- Outcome measures assessing tumor recurrence and longer-term survival rates. These measure concepts have been prioritized in similar medical oncology gap analyses by America's Health Insurance Plans (AHIP) / CMS Core Quality Measure Collaborative and NQF.[101,102]
    - Clinically complex outcome measures require robust risk adjustment or stratification to ensure providers treating patients with very poor prognoses are not penalized inappropriately in accountability programs. This is particularly important for considering patients who are candidates for SBRT, as they are often older or frailer than patients indicated for surgery. Our analysis further identified opportunities to develop PRO measures related to patient satisfaction with shared decision-making related to early access to radiation oncology.
- A structure measure concept assessing the availability and use of multidisciplinary cancer teams in the treatment of NSCLC. Without multidisciplinary review, patients otherwise indicated for SBRT could be inappropriately selected for surgical or drug therapy ("Use of Multidisciplinary Team for Early Stage NSCLC Evaluation").

Telehealth and Remote Patient Monitoring Heart Failure



"Telehealth" refers to a collection of methods for enhancing health care, including care management and health education, using telecommunications technologies.[103] Telehealth facilitates convenient communication and data transmission, which results in improved access to information that is needed for care decisions. Telehealth is particularly helpful for isolated communities and inpatient or post-acute facilities where specialty clinical support is not readily available.[104] It also provides immediate transfer of vital medical data across care settings.[105]

Telehealth encompasses several domains of applications, including:[106]

- **Live videoconferencing:** two-way interaction between a person and provider using audiovisual telecommunications technology
- **Store-and-forward:** transmission of recorded health history through an electronic communications system to a practitioner outside a live interaction
- **Remote patient monitoring (RPM):** transmission of personal health and medical data from an individual in one location via electronic technologies to a provider in a different location for care management
- **Mobile health:** support of health care delivery by communication devices such as cell phones or tablet computers

Telehealth can be used to improve care management and self-management support in various ways. Physician and patient interaction via telemonitoring or using mobile health tools outside of an in-office visit can communicate a patient's symptoms or health status to providers, allowing for redirection of therapy. RPM collects patient symptoms, biometric, and other clinical data via software paired to Bluetooth-enabled peripheral devices or via a wearable or implanted device, providing physiologic data. These data may indicate whether a patient's condition is deteriorating, which can inform care management and triaging, and may also inform population-level health assessments.

Heart Failure and Patient Management

Heart failure is a cardiac condition that occurs when the heart fails to pump blood at a normal rate and volume. Heart failure can cause arrhythmia, venous congestion (such as swelling of the extremities), fatigue stemming from low cardiac output, and breathlessness. Underlying causes of heart failure include coronary artery disease, previous heart attacks, high blood pressure, atrial fibrillation, valvular heart disease, and lifestyle factors such as drug abuse.[107] Heart failure affects nearly 6 million people in the U.S., with 550,000 new cases diagnosed each year.[108] It is a leading cause of hospitalization and readmissions in older adults, and is associated with high costs.[109,110,111]

There are a variety of approaches to heart failure treatment, including pharmacologic and nonpharmacologic interventions and procedures. These may include lifestyle changes such as dietary restrictions, increased physical activity, and weight loss; drug therapies including diuretics, vasodilators, inotropic agents, anticoagulants, beta-blockers, and digoxin; and procedures such as cardiac resynchronization therapy (CRT), pacemakers, implantable cardioverter-defibrillators (ICDs), percutaneous coronary intervention, valve replacement or repair, and ventricular restoration.[112]

CRT and ICDs are considered cardiovascular implantable electronic devices (CIEDs). These technologies can monitor their own functioning and record clinical parameters that are then transmitted to health care providers. This type of RPM offers a safe alternative to in-person device monitoring and can reduce unnecessary follow-up visits.[113] Other RPM interventions can support remote patient engagement and management, including assessment of symptoms and monitoring-guided therapy.

Telehealth for Heart Failure Management

Telehealth solutions have been explored as a method to help patients and providers track early signs of worsening heart failure, avoid adverse consequences, and improve patients' quality of life. While numerous studies and health technology assessments have explored the benefits of these management programs and technologies, clinical guidelines vary on recommendations for their use. Specifically, guidelines for the management of heart failure indicate the following:[114,115,116]

- Heart Rhythm Society (HRS): Recommends a strategy of remote monitoring and interrogation of CIED combined with in-person evaluations over a strategy of in-person evaluation alone. Recommends that all patients with CIED should be offered remote monitoring as part of standard follow-up management strategy. Recommends all patients who have implantable loop recorders with wireless data transfer capability should be enrolled in a remote monitoring program. Does not make a recommendation for RM alone or combined with other diagnostics to manage heart failure, as effectiveness is currently uncertain.
- European Society of Cardiology (ESC): Recommends monitoring of pulmonary pressures using a wireless implantable hemodynamic monitoring system and multiparameter monitoring for certain patients based on ICD data.
- American College of Cardiology Foundation (ACCF) and American Heart Association (AHA): No recommendation for the use of systems of care to promote care coordination for patients with heart failure, including remote telemonitoring programs.

Discern Health's review of telehealth interventions found numerous potential benefits for their use in practice. These benefits include improvements in early identification of issues (deterioration detection, hospitalization risk), improvements in utilization outcomes (reduced hospitalizations, hospital length of stay, and readmissions), and improvements in other important outcomes (mortality, health-related quality of life, change in New York Hospital Association heart failure class).

Heart Failure Quality Landscape

Discern Health identified multiple measurement opportunities within the heart failure episode of care. These included measurement opportunities related to diagnosis (physical examinations and risk scoring assessments, timely tests and imaging), treatment (appropriate prescribing of medications such as angiotensin-converting-enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), beta-blockers, and statins; timely initiation of procedures), monitoring (post-treatment assessments, self-care education), outcomes (hospital admission and readmission rates, complication rates, mortality rates, change in quality of life), and practice structure (initiating RPM programs for patients with CIED, collecting device-reported data for use in management). The full list of measurement opportunities is detailed in Appendix D.

Through its measure scan, Discern Health identified over 40 quality measures related to the heart failure care trajectory. Among these measures were 14 quality measures and one Improvement Activity that directly or indirectly promote appropriate use of remote monitoring for heart failure patients.* The identified process measures assess appropriate response to heart failure symptoms, whether activity levels and clinical data (such as volume overflow and left ventricular ejection fraction (LVEF)) are assessed, and whether implantable devices are monitored on a routine in-person basis. Identified outcome measures assess heart failure-specific admission and readmission rates, all-cause readmission rates, and heart failure mortality rates. In addition, CMS has implemented a practice improvement activity for the MIPS program that promotes use of telehealth services that expand practice access, which could include telemonitoring and RPM for heart failure.

Heart failure's prevalence and cost burden have made it a high priority in VBP programs. Several Medicare VBP programs include the relevant measures that Discern Health identified. Notably, both the HHRP and HIQR programs include measures promoting assessment of cardiac function or heart failure symptoms. Further, the HIQR, HRRP, and MSSP programs all include either all-cause or heart failure-specific readmission measures. A heart failure-specific mortality measure is included in both the HIQR and HVBP programs. The full list of relevant quality measures and their use in VBP models is included in Appendix D.

Measure Gap Priorities

While heart failure has been a significant area of focus for quality measurement, measure gaps remain. The following section describes available measures not used in Medicare VBP models, and measure concepts identified by Discern that, if used in VBP models, would promote higher-value care of patients with heart failure, including the appropriate use of telehealth. Refer to Table 12 for a list of priority available measures to fill gaps in program measure sets, and measure concepts that need to be developed.

* Several excluded measures focus on appropriate use of medications for heart failure patients, such as ACE inhibitors or ARB therapy, but did not relate directly to the appropriate use of telehealth or RPM for heart failure patients.

Table 12. Heart Failure Telehealth Priority Measure Gaps

Domain	Availability	Title	Type	Level of Analysis
Monitoring	Existing *(gap in program measure sets)*	Heart Failure: Symptom and Activity Assessment	Process	Clinician
	Concept *(gap for measure development)*	Flagged Telemonitoring Notifications Resulting in Change in Treatment	Process	Clinician
Treatment	Existing *(gap in program measure sets)*	Heart Failure Symptoms Addressed	Process	Facility
	Concept *(gap for measure development)*	Patient Education Provided for Remote Patient Monitoring	Process	Clinician
	Existing *(gap in program measure sets)*	In-Person Evaluation Following Implantation of Cardiovascular Implantable Electronic Device (CIED)	Process	Clinician
Outcome	Existing *(gap in program measure sets)*	Gains in Patient Activation (PAM) Scores at 12 Months	Outcome	Clinician
	Concept *(gap for measure development)*	Change in Patient-Reported Heart Failure Quality of Life	PRO	Clinician
Structural	Concept *(gap for measure development)*	Rate of Enrollment in Remote Patient Telehealth Monitoring Services for Chronically Ill Patients	Structural	Facility
	Concept *(gap for measure development)*	Rate of Activation of RM Services for Eligible Patients with CIED	Structural	Facility

Gaps in Program Measure Sets

As detailed in Table 12, Discern Health identified available measures relevant to the heart failure treatment episode that are not currently used in VBP measure sets, or which could be modified for broader use. These include:

- Measures promoting appropriate assessment of heart failure patients' symptoms and activity, which can be supported through use of telehealth ("Heart Failure: Symptom and Activity Assessment").
- A home health measure assessing whether heart failure patients who exhibited symptoms were treated accordingly, and which can be supported through use of telehealth ("Heart Failure Symptoms Addressed"). While this measure is currently in use in the HHQR, there is a gap in assessing whether heart failure symptoms were addressed for patients in other care settings.
- A measure assessing timely in-person evaluations for patients receiving a CIED to monitor device function, which directly promotes appropriate monitoring of implantable devices that can support RPM ("In-Person Evaluation Following Implantation of Cardiovascular Implantable Electronic Device (CIED)").
- An outcome measure assessing whether patients made gains in patient activation, or self-management, during treatment, which telehealth services can help improve ("Gains in Patient Activation (PAM) Scores at 12 Months").

Gaps for Measure Development

There are numerous gaps in available measures related to the use of telehealth for heart failure management. Measure concepts that can fill these gaps, and which are detailed in Table 12, include:

- Structural measure concepts to ensure that appropriate patients are enrolled in remote telehealth systems. This may include telemonitoring-based systems that increase patient access to primary care or cardiologists, or it may include remote monitoring systems for patients with CIEDs ("Rate of Enrollment in Remote Patient Telehealth Monitoring Services for Chronically Ill Patients").
    - For the latter group, an additional structural measure to monitor rates at which CIED patient data transfer is activated for use by physicians can help ensure that there are not missed opportunities in data tracking ("Rate of Activation of RM Services for Eligible Patients with CIED").
- A process measure concept assessing timely and appropriate provision of patient education for remote monitoring to ensure that patients are prepared for self-management and understand the device and its capabilities ("Patient Education Provided for Remote Patient Monitoring").
- A process measure concept assessing whether telehealth monitoring resulted in changes to patient management, and specifically where flagged notifications from telemonitoring or device-reported data resulted in a change in treatment ("Flagged Telemonitoring Notifications Resulting in Change in Treatment")
- A PRO performance measure concept for patients with heart failure assessing changes over time in functional outcomes and quality of life ("Change in Patient-Reported Heart Failure Quality of Life"). Heart failure-specific PRO tools exist, and their viability in accountability programs should be explored as appropriate use of telehealth can address health-related quality of life issues.[117] As with all PRO performance measures, the feasibility of collecting measure data and ensuring adequate risk adjustment for fairness of these measures is essential to ensure providers are not held accountable for gaps in care outside of their control. This is particularly important for heart failure care, where patients may have multiple co-morbidities impacting their quality of life.

Cross-Cutting Findings

In reviewing each of the illustrative medical technology topics, Discern Health identified areas where quality measure gaps impacted multiple topics. These cross-cutting gaps may extend beyond the illustrative topics and impact other technologies not examined in this review.

Because policymakers seek to develop parsimonious measure sets, measures that address cross-cutting gaps are often preferable to an overabundance of process measures, if the cross-cutting measures assess important performance issues that impact a large population of patients. Below, we discuss key cross-cutting issues that warrant further review to fill important gaps.

Patient-Reported Outcomes: PROs and other measures of patient experience are a stated priority for CMS and other payers.[118] PRO Performance Measures (PRO-PMs) link changes in patient-reported health issues such as health status, functional status, or quality of life to provider accountability. Initiatives like the National Institutes for Health's PRO Measurement Information System (PROMIS) and organizations like the International Consortium for Health Outcomes Measurement (ICHOM) have identified key indicators in patient health status and quality of life that could contribute to PRO performance measurement. ICHOM's work includes outcomes for many of the conditions impacted by medical technology, including IBD, heart failure, lung cancer, and osteoarthritis.[119,120,121,122]

- PROs offer a valuable way to capture patient-centered data about changes in health status resulting from appropriate use of various medical technologies. Patient-reported data about perceived access to tests that accurately categorize disease or illness, and whether they felt tests were provided in a timely manner, can help inform whether diagnostics are effectively utilized.
- PROs and patient experience measures that assess whether treatment planning and shared decision-making occurred can convey patients' perspectives on whether providers shared the detail needed to inform decisions about tests and services to meet patient needs and preferences. PROs can encourage provider accountability for engaging patients as partners and help ensure that technologies at risk for underuse in VBP models are presented to patients as options.
- Measures and incentives for promoting PRO data collection exist, such as USWR measures for chronic wound care or the voluntary PRO data submission component of the CJR model. In other cases, PRO-PMs are available to report, but are not required; for example, functional outcome measures, such as CMS' "Functional Outcome Assessment" measure, are included in the MIPS measure menu.

Unnecessary Utilization of Health Care Services: There is evidence that many of the technologies reviewed can reduce hospital utilization if used appropriately. Many VBP models assess hospital admissions and readmissions. Moreover, reducing length of stay is a high priority for hospitals under the incentives of the Medicare Diagnosis-Related Groups episode-based payment system.

Gaps in utilization measurement include:

- **Length of Stay:** Hospital length of stay (LOS) is an important indicator that may improve with appropriate use of technology. While ICU and inpatient LOS measures are available, they are not currently in Medicare VBP program use. NQF has indicated that existing LOS measures lack reliability and require refinements to risk adjustment methodologies.[123,124] Condition-specific LOS measures should be explored to ensure that the measures allow for drill-down to better understand quality issues related to care for specific populations.[125]

- **Unplanned Re-Operations:** Certain surgical or implantable technologies, such as minimally invasive surgery or case-matched hip or knee implants, offer benefits for avoiding re-operations. While re-operation measures are available, such as the American College of Surgeons' "Unplanned Reoperation Within the 30-Day Postoperative Period" measure, they assess a relatively short time horizon. Additional measures that reflect longer timeframes or multi-year results are needed.

Surgical Outcomes: Surgical outcome measures impact a diverse range of disciplines, procedures, and technologies. While Medicare VBP models incorporate some surgical outcome measures, those measures are focused on short-term issues, such as 30-day complications and readmissions, and are not broadly inclusive of a comprehensive set of surgeries.

- Post-surgical functional status is an important indicator of outcomes that are most meaningful to patients. While measures currently exist for assessing change in function following joint arthroplasty, other procedures, such as post-colectomy return of normal bowel function, do not have functional outcome measures.

- Post-surgical infections or infections that extend into the post-acute treatment phase following surgery are another important gap. While surgical site infection measures exist, their use in VBP measure sets is limited. Medical technologies, including laparoscopic tools and negative pressure wound therapy, have been demonstrated to improve infection rates in surgical cases and chronic wound care.[126,127]

- Shared decision-making and accountability for surgery or post-surgical treatment is also an important domain of measurement not currently assessed in VBP measure sets. Shared decision-making helps ensure that providers communicate a range of options, including more and less expensive options, in determining the types of procedures patients choose to receive or forgo.

Device-Reported Data Capture and Use: Increasingly, wearable or implantable devices are available to collect and transmit clinical data to providers. Availability of this type of data creates an opportunity for structural measures to assess whether providers are utilizing device-reported data appropriately to monitor patient health and guide care.

- Device-reported data can include clinical data points (e.g., blood glucose readings, INR values) that providers can use to interpret health status and redirect care management, and patient-reported data, such as patients' periodic reporting of their health status.

- Collection and use of device-reported data for both population health and care management purposes could fulfill the definition of a practice improvement activity under the MIPS Improvement Activities performance category.

RECOMMENDATIONS AND NEXT STEPS

Health care stakeholders, including payers, providers, patients, policymakers, and medical technology manufacturers, all play important roles in prioritizing and defining effective quality measures for use in VBP models. Payers direct measurement priorities through incentive payment model design. Medical professional societies specify clinical practice guidelines that form the basis for quality measures. Through participation in quality organizations like NQF, stakeholders work together to define gaps and recommendations for improving VBP measure sets.

Medical technology manufacturers can support the work of improving quality measures and program measure sets by being informed and engaged, and by leveraging their expertise to address the evidence and performance gaps related to their products. They can also proactively work with payers, medical professional societies, and other measure developers to ensure that meaningful and effective measures are developed to reflect patient priorities and the value that innovative medical technology products can bring to health care.

This white paper recommends strategies and next steps that policymakers, professional societies, manufacturers, and other stakeholders should undertake in collaboration to fill quality measure gaps.

1. **Prioritize Gaps.** Measure developers and policymakers, including CMS, should prioritize the gaps identified in this report as areas for measure enhancement. The gaps identified align with the priorities defined under the National Quality Strategy and in CMS' Measure Development Plan. Other important gaps beyond those defined in this report should also be explored using a similar methodology.

   - 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

2. **Enhance Evidence.** Stakeholders should collaborate to develop robust evidence that demonstrates the total value, including quality and cost over time, of technology.

- 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

3. **Develop New Measures to Fill Gaps.** Measure developers should use the priority gaps identified in this report to specify and test new measures. In particular, developers should consider the importance of cross-cutting measures that align with CMS' priorities, including PROs and structural measures, such as MIPS improvement activities that promote patient-centered use of medical technologies.

- 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

4. **Leverage Existing Measures for VBP Models.** This report identifies existing quality measures not currently used in VBP models. Policymakers should review the utility of these measures and work with stewards to address gaps in feasibility or testing.

- 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

5. **Incorporate Newly Developed Measures into VBP Models.** Policymakers and payers should revise existing VBP model measure sets to incorporate newly developed measures that address the priority concepts identified in this report.

- 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 priority new 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

APPENDICES

A. Overview of Value-Based Payment Incentives[128,129]

Financial Incentives	Description	Example
Fee-for-Service (FFS)	In FFS models, a predetermined amount is paid for each service a provider or group of providers delivers regardless of quality, outcomes, or efficiency.	Medicare Fee-for-Service
Pay-for-Reporting (P4R)	In P4R models, providers receive financial incentives (e.g., an adjustment to scheduled increases in FFS payment) for reporting quality or cost data to payers. P4R data may also be used for public accountability purposes.	Hospital Inpatient Quality Reporting (HIQR) Program
Pay-for-Performance (P4P)	In P4P models, providers receive financial incentives for achieving improved performance through increased quality of care and/or reduced costs. Like P4R, incentives are usually applied on top of FFS payments and may be publicly reported.	Merit-based Incentive Payment System (MIPS)
Episode-Based Payment	In episode-based payment models (also referred to as "bundled payment"), providers receive a single payment for all the services needed by a patient during an entire episode of care, such as a hospitalization for an elective procedure.	Comprehensive Care for Joint Replacement (CJR) Model
Shared Savings	In shared savings models, payers incentivize providers to reduce unnecessary health care spending for a defined population of patients or for an episode of care by offering them a percentage of any realized savings (one-sided risk), and by putting them at risk to repay a percentage of net losses through overspending (two-sided risk). Savings or losses are measured as the difference between expected and actual cost during a given performance period. Achievement of shared savings is typically tied to quality performance.	Medicare Shared Savings Program (MSSP)
Capitation	Under capitated models, a provider or group of providers receives a single payment to cover all the services patients need during a specific period, independent of how many or few episodes of care are provided.	Medicare Advantage
Partial Capitation	As in capitated models, partial capitated models reimburse providers with a fixed dollar payment for the specific portion of the services that patients receive in each period. Non-specified services remain reimbursed under FFS.	Chronic Care Management (CCM) enhanced fee

B. Selected Medical Technology Topics and Clinical Areas

Topic	Technology Topic				Clinical Area		
	Frequent / Costly[25]	High-Cost Supply[26]	High-Cost Capital[27]	High-Cost Illness[19,20]	High-Mortality / Complication[21,22]	Priority Chronic[23]	High-Impact Medicare[24]
CGM and SAP for T1D	✓	✓	✓	✓		✓	✓
Diagnostic Testing to Prevent AMR for CAP	✓	✓					
Hip and Knee Implants for THA/TKA	✓	✓	✓	✓	✓	✓	✓
Minimally Invasive Colectomy for IBD		✓			✓		
NPWT for Chronic Wound Care	✓			✓	✓		
PT INR Home Testing for PE		✓					
SBRT for NSCLC		✓	✓	✓		✓	✓
Telehealth and RPM for Heart Failure	✓	✓	✓	✓	✓	✓	✓

C. Overview of Value-Based Payment Models

Model	Overview	Incentives	Participants	Measures (As of June 2017)
Medicare Programs				
Ambulatory Surgical Center Quality Reporting (ASCQR)[130]	ASCs report quality of care data for standardized measures to receive a full annual update to their annual payment rate.	Pay-for-Reporting	ASCs	12 measures
Home Health Quality Reporting (HHQR) Program[131]	Home Health agencies report health care quality data to avoid reductions to market basket percentage increases.	Pay-for-Reporting	Home Health Agencies	45 measures
Hospice Quality Reporting (HQRP) Program[132]	Hospice facilities report health care quality data to avoid reductions to market basket percentage increases.	Pay-for-Reporting	Hospice Facilities	9 measures
Hospital Acquired Condition Reduction Program (HAC-R)[133]	CMS reduces payments to applicable hospitals that rank in the worst-performing quartile with respect to risk-adjusted HAC measures.	Pay-for-Performance	Hospitals	6 measures
Hospital Inpatient Quality Reporting (HIQR) Program[134]	CMS pays hospitals that do not successfully report designated quality measures receive a reduction to annual market basket updates.	Pay-for-Reporting	Hospitals	41 measures
Hospital Outpatient Quality Reporting (HOQR)[135]	Hospitals that do not meet administrative, data collection and submission, validation, and publication requirements receive a point reduction in their annual payment update under the Outpatient Prospective Payment System.	Pay-for-Reporting	Hospitals	26 measures
Hospital Readmission Reduction Program (HRRP)[136]	CMS reduces payments to Inpatient Prospective Payment System hospitals with excess readmissions, defined as a hospital's readmission performance compared to the national average for the hospital's set of patients with that applicable condition.	Pay-for-Performance	Hospitals	6 measures
Hospital Value-Based Purchasing (HVBP)[137]	CMS adjusts payments to hospitals under the Inpatient Prospective Payment System based on reported quality and resource use measures.	Pay-for-Performance	Hospitals	21 measures
Long-Term Care Hospital Quality Reporting (LTCHQR)[138]	LTCHs must report quality data to CMS to avoid a reduction in annual payment updates.	Pay-for-Reporting	LTCHs	13 measures
Medicare Shared Savings Program (MSSP)[139]	Accountable Care Organizations (ACOs) receive shared savings or losses depending on quality performance and spending against a financial benchmark.	Shared Savings	ACOs	31 measures
Merit-Based Incentive Payment System (MIPS)[140]	Physicians earn a performance-based payment adjustment, based on data reported or collected across four Performance Categories: Quality, Improvement Activities, Advancing Care Information, and Cost.	Pay-for-Performance	Physicians and Alternative Payment Model (APM) Entities	270+ quality measures 90+ Improvement Activities 15 ACI measures

Model	Overview	Incentives	Participants	Measures (As of June 2017)
Medicare Programs				
Nursing Home Quality Initiative (NHQI)[141]	CMS provides consumer and providers information regarding the quality of care in nursing homes.	Public Reporting	Nursing Home Facilities	18 measures
Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR)[142]	As a condition for Medicare participation, PPS-exempt cancer hospitals submit quality measure data to CMS for public display.	Public Reporting	PPS-Exempt Cancer Hospitals	17 measures
Skilled Nursing Facility Quality Reporting (SNFQR) Program	Skilled Nursing Facilities (SNFs) report quality data to CMS to avoid a reduction in annual payment updates.	Pay-for-Reporting	SNFs	6 measures
Skilled Nursing Facility Value-Based Purchasing (SNFVBP)	CMS pays SNFs for their services based on the quality of care delivered.	Pay-for-Performance	SNFs	2 measures
Centers for Medicare & Medicaid Innovation (CMMI) Medicare Demonstration Models				
Bundled Payments for Care Improvement (BPCI) Initiative[143]	Hospitals voluntarily participating receive retrospective or prospective (depending on the model) bundled payments for selected episodes of care.	Episode-Based Payment	Hospitals	HIQR and HOQR measures
Comprehensive Care for Joint Replacement (CJR) Model	CMMI holds hospitals in selected service areas financially accountable for the cost of a CJR episode of care under this mandatory model, depending on quality performance.	Episode-Based Payment	Hospitals performing hip or knee replacement	2 measures
Comprehensive Primary Care (CPC)[144] / Plus (CPC+)[145]	Primary care practices voluntarily participating receive monthly non-visit-based care management fees and have the opportunity to share in any net savings to the Medicare program.	Enhanced FFS payment / Shared Savings	Primary Care Practices	12 measures
Home Health Value-Based Purchasing (HHVBP)[146]	Home Health agencies compete on value and receive performance-based payment adjustments through 2022.	Pay-for-Performance	Home Health Agencies	24 measures
Next Generation ACO (NGACO) Model[147]	Accountable Care Organizations (ACOs) voluntarily participating receive shared savings or losses depending on quality performance and spending against a quality adjusted prospective financial benchmark.	Shared Savings	ACOs	30 measures
Oncology Care Model (OCM)[148]	Physician practices voluntarily participating enter into payment arrangements that include financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients.	Episode-Based Payment	Oncology Specialty Practices	12 measures

D. Medical Technology Gap Analysis Results

Continuous Glucose Monitoring & Sensor-Augmented Insulin Pumps for Type 1 Diabetes

Guidelines Assessed

Year	Organization	Title
2016	American Diabetes Association (ADA)	Standards of Medical Care in Diabetes ■ Classification and Diagnosis of Diabetes ■ Glycemic Targets ■ Approaches to Glycemic Treatment
2016	Endocrine Society	Diabetes Technology – Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults
2012		Management of Hyperglycemia in Hospitalized Patients in Non-Critical Care Setting
2009		Evaluation and Management of Adult Hypoglycemic Disorders
2017	American Association of Clinical Endocrinologists (AACE) / American College of Endocrinology (ACE)	Comprehensive Type 2 Diabetes Management Algorithm – Executive Summary
2015		Clinical Practice Guidelines for Developing a Diabetes Mellitus Comprehensive Care Plan

Clinical Recommendations

Guideline	Clinical Issue	Recommendation	Strength of Recommendation
ADA	Glycemic Targets	*Recommended.* Use CGM with intensive insulin regimens to lower A1C in adults with Type 1 Diabetes	Level A [Clear evidence from well-conducted, generalizable RCTs]
	Approaches to Glycemic Treatment	*Recommended.* Intensive management through pump therapy/CGM should be strongly encouraged	
AACE/ACE	Managing Glycemia in T1D	*Recommended.* Continuous subcutaneous insulin infusion to provide a more physiologic way to deliver insulin	Grade A; BEL 1
	Monitoring Glucose	*Recommended.* CGM should be considered for patients with T1D and T2D on basal-bolus therapy to improve A1C levels and reduce hypoglycemia	Grade B; BEL 2
	Insulin Pump Use	*Recommended.* Insulin pump therapy should only be used in patients who are motivated and knowledgeable in diabetes self-care, including insulin adjustment. Sensor-augmented therapy, including that with a threshold-suspend function, should be considered for patients who are at risk for hypoglycemia	Grade A; BEL 1

Benefits of CGM and SAP

Benefit[149,150,151,152]
■ Durable or rapid reduction of HbA1c levels ■ Fewer hypoglycemia episodes / Reduction of severe hypoglycemia ■ Increased length of time of glycemic control ■ Improved glycemia ■ Delayed onset of retinopathy, nephropathy, and neuropathy progression

Type 1 Diabetes Measurement Opportunities

Domain	Type	Opportunity
Diagnosis	Process	Family History Collected
	Process	BMI Assessment Conducted
	Process	HbA1c Testing Conducted
	Process	LDL-C Testing Conducted
Treatment	Process	Lifestyle Counseling Performed
	Process	Intensive Insulin Therapy Initiated
	Process	Appropriate Glucagon Prescribing
Monitoring	Process	Blood Glucose Testing Performed/Monitored
	Process	HbA1c Testing Performed
	Process	BMI Monitored
	Process	Other Monitoring (Foot Exam / Eye Exam / Nephropathy)
Outcomes	Outcome	Rate of Hypoglycemic Events
	Outcome	Rate of Hyperglycemic / Ketoacidosis Events
	PRO	Patient-Reported Quality of Life
	Outcome	Rate of Glycemic Control
	Outcome	Percentage of Therapeutic Time in Range (TTR)
Structural	Structural	Device Competency Tested
	Structural	Collection of Device-Reported Patient Data

Identified Quality Measures Relevant to CGM and SAP

ID	Measure Title	Type	Level of Analysis	Steward	Program Use
0057	Comprehensive Diabetes Care: HbA1c Testing	Process	Health Plan	NCQA	
0060*	HbA1c Testing for Pediatric Patients	Process	Clinician	NCQA	
0603*	Adult(s) Taking Insulin with Evidence of Self-Monitoring Blood Glucose Testing	Process	Clinician / Facility / Health Plan / Population	Optum	
0059	Comprehensive Diabetes Care: HbA1c Poor Control (>9.0%)	Outcome	Health Plan	NCQA	MIPS MSSP Part C Star Ratings
0575	Comprehensive Diabetes Care: HbA1c Control (<8.0%)	Outcome	Health Plan	NCQA	
2362	Glycemic Control – Hyperglycemia	Outcome	Facility	CMS	
2363	Glycemic Control – Hypoglycemia	Outcome	Facility	CMS	
0272 PQI 01	Diabetes Short-Term Complications Admission Rate	Outcome	Population	AHRQ	
0274 PQI 03	Diabetes Long-Term Complications Admission Rate	Outcome	Population	AHRQ	
0638	Uncontrolled Diabetes Admission Rate	Outcome	Population	AHRQ	
N/A	All-Cause Unplanned Admissions for Patients with Diabetes	Outcome	Facility	CMS	MSSP
N/A	All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions	Outcome	Facility	CMS	MSSP

ID	Measure Title	Type	Level of Analysis	Steward	Program Use
1789	Hospital-Wide All-Cause Unplanned Readmission Measure	Outcome	Facility	CMS	MIPS HIQR MSSP
2393	Pediatric All-Condition Readmission Measure	Outcome	Facility	CEPQM	
IA BMH 1	Diabetes Screening	Improvement Activity	Clinician	CMS	MIPS
IA PM 4	Glycemic Management Services	Improvement Activity	Clinician	CMS	MIPS
IA PM 13	Chronic Care and Preventative Care Management for Empaneled Patients	Improvement Activity	Clinician	CMS	MIPS

* Endorsement Removed

Remaining Measurement Gaps Relevant to CGM and SAP

Domain	Type	Level of Analysis	Gap
Treatment	Process	Clinician	Intensive Insulin Therapy (CGM / SAP) Prescribing
Outcomes	Outcome	Clinician / Facility / Health Plan	Blood Glucose Time in Range (TIR)
	PRO	Clinician / Facility	Patient-Reported T1D Quality of Life
	PRO	Clinician / Facility	Patient-Reported Incidence of Hypoglycemia
	PRO	Clinician / Facility	Patient-Reported Satisfaction with Insulin Delivery Device
Structural	Structural	Clinician / Facility	Implementation of Systems to Capture and Utilize Device-Reported Data

Diagnostic Testing to Prevent Antimicrobial Resistance for Community-Acquired Pneumonia

Guidelines Assessed

Year	Organization	Title
2015	Taskforce for Combatting Antibiotic-Resistant Bacteria	The National Action Plan for Combating Antibiotic Resistant Bacteria
2014	National Institute for Health and Care Excellence (NICE)	Pneumonia in Adults: Diagnosis and Management
2011	European Respiratory Society (ERS) / European Society for Clinical Microbiology and Infectious Diseases (ESCMID)	Guidelines for the Management of Adult Lower Respiratory Tract Infections
2011	British Thoracic Society (BTS)	Guidelines for the Management of Community-Acquired Pneumonia in Children
2009		Guidelines for the Management of Community-Acquired Pneumonia in Adults (Update)
2007	Infectious Diseases Society of America (IDSA) / Society for Healthcare Epidemiology of America (SHEA)	Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship
2007	IDSA / American Thoracic Society (ATS)	Guidelines on the Management of Community-Acquired Pneumonia in Adults
2011	Pediatric Infectious Diseases Society (PIDS) / IDSA	The Management of Community-Acquired Pneumonia in Infants and Children Older than 3 Months of Age

Clinical Recommendations

Guideline	Clinical Issue	Recommendation	Strength of Recommendation
ERS/ ESCMID (2011)	Quantitative molecular testing in hospital (*S. pneumoniae*, influenza, RSV and atypical pathogens)	*Recommended.* For CAP patients in whom antibiotic therapy has been initiated (*S. pneumoniae*) and during the winter season if tests can be validated and results obtained rapidly (viral)	A3
BTS (2009)	PCR for M. pneumonia, *C. pneumoniae*, and respiratory viruses and atypical pathogens in hospital	*Recommended.* As a method of choice for adult patients in hospital, for high severity CAP with strong suspicion of psittacosis (*C. pneumoniae*)	D [Other information]
BTS (2011)	Microbiological investigations, including blood culture, NP secretions and/or nasal swabs for viral detection by PCR and/or immunofluorescence, serology for respiratory viruses, *M. pneumoniae* and *C. pneumoniae*, and pleural fluid for microscopy, culture, antigen detection, and/or PCR	*Recommended.* Should be attempted in children with severe pneumonia sufficient to require pediatric intensive care admission or those with complications of CAP *Not Recommended.* Should not be considered routinely in children with milder disease or those treated in the community	C [Formal combination of expert views]
IDSA / ATS (2007)	Diagnostic tests for specific pathogens altering standard management	*Recommended.* Patients with CAP should be investigated with presence of pathogens suspected	Strong [Level II evidence]
	Etiologic diagnostic tests (for patients meeting clinical factors)	*Recommended.* Testing is recommended where optional based on clinical indication	Moderate [Level I, II, and III evidence]
PIDS / IDSA (2011)	Rapid testing for influenza to avoid antibiotic testing	*Recommended.* Use tests for the rapid diagnosis of influenza to evaluate children with CAP	Strong [High-quality evidence]
	Testing for *M. pneumoniae*	*Recommended.* Children with suspicious signs and symptoms should be tested to guide antibiotic selection	Weak [Moderate-quality evidence]
	Testing for *C. pneumoniae*	*Not Recommended.* Reliable and readily available diagnostic tests do not currently exist	Strong [High-quality evidence]

Benefits of Rapid Diagnostic Testing

Benefit[153,154,155,156,157,158,159,160,161,162,163,164,165]
■ Improved prediction of bacteremia
■ Reduced ICU admissions
■ Reduced inpatient admissions
■ Reduced length of stay
■ Reduced all-cause mortality
■ Accurate selection of empirical narrow-spectrum antibiotics
■ Accurate discrimination between viral and bacterial pathogens
■ High sensitivity and/or specificity
■ Reduced time to detection / diagnosis
■ Lower cost

Community-Acquired Pneumonia (CAP) Measurement Opportunities

Domain	Type	Opportunity
Prevention	Process	Timely Immunizations and Vaccinations
	Process	Implementation of Smoking Cessation
Diagnosis	Process	Illness Severity Scoring / Risk Assessment
	Process	Chest Imaging
	Process	Timely Initiation of Biomarker Assessment
	Process	Timely Collection of Blood / Sputum Samples / Respiratory Samples for PCR
Treatment	Process	Timely Initiation of Empiric Antibiotics
	Process	Avoidance of Inappropriate Antibiotic Use
	Process	Avoiding Inappropriate Antibiotic Dosing
	Process	Timely Initiation of Narrow / Pathogen-Directed Antibiotics
	Process	Timely Step-Down to Oral Antibiotic Therapy
	Process	Timely Initiation of Non-Antibiotic Treatment(s)
Monitoring	Process	Assessment / Classification of Failure Response
	Process	Coordination of Discharge and Follow-Up Review
Outcomes	Outcome	Pneumonia Admission Rate
	Outcome	Pneumonia Readmission Rate
	Outcome	Pneumonia Mortality Rate
	Outcome	Duration of Antibiotic Therapy
	Outcome	Treatment Failure Rate
	Outcome	Identification of Antibiotic Resistance
	Outcome	Hospital Length of Stay
Structural	Structural	Antimicrobial Stewardship Program
	Structural	Clinical Decision Support / Ordering Systems
	Structural	Antimicrobial Use Audit

Identified Quality Measures Relevant to Diagnostic Testing

ID	Measure Title	Type	Level of Analysis	Steward	Program Use
0002	Appropriate Testing for Children with Pharyngitis	Process	Health Plan	NCQA	MIPS
0148	Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital	Process	Facility	CMS	
0356	PN3a – Blood Cultures Performed Within 24 Hours Prior to or 24 Hours After Hospital Arrival for Patients Who Were Transferred or Admitted to the ICU Within 24 Hours of Hospital Arrival	Process	Facility	CMS	
0232	Vital Signs for Community-Acquired Bacterial Pneumonia	Process	Clinician	AMA-PCPI	
0058	Avoidance of Antibiotic Treatment in Adults with Acute Bronchitis	Process	Health Plan	NCQA	MIPS
0069	Appropriate Treatment for Children with Upper Respiratory Infection (URI)	Process	Health Plan	NCQA	MIPS
2720	National Healthcare Safety Network (NHSN) Antimicrobial Use Measure	Process	Facility	CDC	
0096	Community-Acquired Bacterial Pneumonia (CAP): Empiric Antibiotic	Process	Clinician	AMA-PCPI	
0147	Initial Antibiotic Selection for Community-Acquired Bacterial Pneumonia (CAP) in Immunocompetent Patients	Process	Facility	CMS	HIQR HVBP
0151	Initial Antibiotic Received Within 6 Hours of Hospital Arrival	Process	Facility	CMS	
1716	NHSN Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus Aureus* (MRSA) Bacteremia Outcome Measure	Outcome	Facility / Population	CDC	HAC-R HVBP LTCHQR
1717	NHSN Facility-Wide Inpatient Hospital-Onset *Clostridium Difficile* Infection (CDI) Outcome Measure	Outcome	Facility / Population	CDC	HAC-R HVBP LTCHQR
0231 IQI 20	Pneumonia Mortality Rate	Outcome	Facility	AHRQ	
0468	Hospital 30-day, All-Cause Risk Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization	Outcome	Facility	CMS	HIQR HVBP
0708	Proportion of Patients Hospitalized with Pneumonia that have a Potentially Avoidable Complication (During the Index Stay or the 30-Day Post-Discharge Period)	Outcome	Facility / Health Plan / Population	BTE	
0140	Ventilator-Associated Pneumonia for ICU and High-Risk Nursery (HRN) Patients	Outcome	Facility	CDC	
0506	Hospital 30-Day, All-Cause, Risk Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization	Outcome	Facility	CMS	HIQR HRRP
2882	Excess Days in Acute Care After Hospitalization for Pneumonia	Outcome	Facility	CMS	HIQR
2414	Pediatric Lower Respiratory Infection Readmission Measure	Outcome	Facility	CEPQM	
0331	Severity-Standardized Average Length of Stay – Routine Care (Risk-Adjusted)	Outcome	Facility	Leapfrog Group	
0332	Severity-Standardized ALOS – Special Care	Outcome	Facility	Leapfrog Group	
0328	Case-Mix-Adjusted Inpatient Hospital Average Length of Stay	Outcome	Facility	UHG	
0702	Intensive Care Unit (ICU) Length of Stay (LOS)	Outcome	Facility	PRLIHPS	
2393	Pediatric All-Condition Readmission Measure	Outcome	Facility	CEPQM	

ID	Measure Title	Type	Level of Analysis	Steward	Program Use
1789	Hospital-Wide All-Cause Unplanned Readmission Measure	Outcome	Facility	CMS	HIQR MSSP
N/A	Antibiotic Utilization: Summary of Outpatient Utilization of Antibiotic Prescriptions During the Measurement Year, Stratified by Age and Gender	Outcome	Health Plan	NCQA	
1611	Episode Treatment Group (ETG) Based Pneumonia Cost of Care Measure	Outcome	Clinician / Facility / Health Plan / Population	Optum	
2579	Hospital-Level Risk-Standardized Payment Associated with a 30-Day Episode of Care for Pneumonia	Outcome	Facility	CMS	
IA PSPA 15	Implementation of Antibiotic Stewardship Program	Improvement Activity	Clinician	CMS	MIPS

Remaining Measurement Gaps Relevant to Diagnostic Testing

Domain	Type	Level of Analysis	Gap
Diagnosis	Process	Clinician	Risk Severity Screening for Pneumonia Performed
	Process	Clinician / Facility	Timely Molecular Assessment of Pathogen in Severe CAP
	Process	Clinician / Facility	Point-of-Care Testing for Pathogen Identification to Guide Same-Day Treatment
Treatment	Process	Clinician / Facility	Selection, Dosing, and Duration of Antibiotic Treatment
	Process	Clinician / Facility	Timely De-Escalation of Antibiotic Therapy
	Outcome	Facility	Frequency of Identified Pathogen
	Outcome	Facility	Frequency of Identified Multidrug Resistant Cases
Structural	Structural	Facility	Implementation of Prospective Antimicrobial Use Audit / Frequency of Review
	Structural	Facility	Implementation of Antibiotic Clinical Decision-Support (CDS) / Order Entry

Hip and Knee Implants for Total Hip or Knee Replacement

Guidelines Assessed

Year	Organization	Title
2015	American College of Radiology (ACR)	ACR Appropriateness Criteria® Imaging After Total Hip Arthroplasty
2011		ACR Appropriateness Criteria® Imaging After Total Knee Arthroplasty
2016	American Academy of Orthopaedic Surgeons (AAOS)	Appropriate Use Criteria for the Surgical Management of Osteoarthritis of the Knee
2015		Surgical Management of Osteoarthritis of the Knee
2014		Management of Hip Fractures in the Elderly
2013		Treatment of Osteoarthritis of the Knee
2012		Prevention of Orthopaedic Implant Infection in Patients Undergoing Dental Procedures
2011		Preventing Venous Thromboembolic Disease in Patients Undergoing Elective Hip and Knee Arthroplasty
2013	American College of Rheumatology / American Association of Hip and Knee Surgeons	Perioperative Management of Rheumatic Disease Medications in Total Joint Arthroplasty of the Hip and Knee
2012	American College of Rheumatology	Recommendations for the Use of Nonpharmacologic and Pharmacologic Therapies in Osteoarthritis of the Hand, Hip and Knee
2011	American College of Occupational and Environmental Medicine	Hip and Groin Disorders
2011		Knee Disorders
2003	Agency for Healthcare Research and Quality (AHRQ)	Total Knee Replacement: Evidence Report / Technology Assessment No. 86
2009	American Physical Therapy Association	Hip Pain and Mobility Deficits – Hip Osteoarthritis
2013	Infectious Diseases Society of America (IDSA)	Diagnosis and Management of Prosthetic Joint Infection

Clinical Recommendations

Guideline	Clinical Issue	Recommendation	Strength of Recommendation
AAOS (Knee)	Cruciate retaining knee implants	*No Recommendation*. No difference in outcomes.	Strong recommendation, "high" strength studies with consistent findings
	Polyethylene tibial knee implants		
	Cemented or cementless femoral or tibial components (knee)		
	All cemented or cementless components or hybrid fixation (knee)		Moderate/limited recommendation, "moderate" strength studies with consistent findings
AAOS (Hip)	Cemented femoral stems (hip)	*Recommended*. Use in patients undergoing arthroplasty for femoral neck fractures.	Moderate evidence, "moderate" strength studies with consistent findings
	Cephalomedullary device (hip)	*Recommended*. Use in patients with stable or unstable intertrochanteric fractures; subtrochanteric or reverse obliquity fractures	

Benefits of Hip and Knee Implants

Benefit[166,167,168,169,170]
■ Reduced aseptic revision rates (knee)
■ Reduced revision rates (hip)
■ Preservation of bone stock (knee)
■ Reduced implant-related failure rate (knee)
■ Improved implant performance and durability (knee))
■ Reduced perioperative femoral fracture (hip)

Hip and Knee Arthroplasty (THA/TKA) Measurement Opportunities

Domain	Type	Opportunity
Diagnosis	Process	Physical assessment performed
	Process	Imaging conducted
	Process	Risk assessment performed
	Process	Functionality assessment performed
Treatment	Process	Patient education provided
	Process	Physical therapy referrals provided
	Process	Initiation of corticosteroid therapy
	Process	Initiation of hip resurfacing
	Process	Initiation of knee arthroscopy
	Process	Initiation of hip or knee replacement
Monitoring	Process	Imaging conducted
	Process	Physical therapy and rehabilitation referrals provided
Outcome	Outcome	Rate of post-surgical complications
	Outcome	Patient-reported change in pain/quality of life
	Outcome	Patient-reported change in functionality
	Outcome	Post-surgical revision rate

Identified Quality Measures Relevant to Hip and Knee Implants

ID	Measure Title	Type	Level of Analysis	Steward	Program Use
N/A	Physical Examination	Process	Clinician	AMA-PCPI	
N/A	Identification of Implanted Prosthesis in Operative Report	Process	Clinician	AMA-PCPI	MIPS
N/A	Functional Status Assessment for Total Hip Replacement	Process	Clinician / Facility	CMS	MIPS
N/A	Functional Status Assessment for Total Knee Replacement	Process	Clinician / Facility	CMS	MIPS
N/A	THA/TKA Voluntary PRO and Limited Risk Variable Data Submission	Process	Facility	CMS	CJR
N/A	Functional Outcome Assessment	Process	Clinician / Facility	CMS	MIPS
1609	ETG Based Hip/Knee Replacement Cost of Care Measure	Outcome	Clinician / Facility Health Plan / Population	Optum	
N/A	Hip Replacement or Repair [Episode cost]	Outcome	Clinician	CMS	MIPS
N/A	Knee Arthroplasty (Replacement) [Episode cost]	Outcome	Clinician	CMS	MIPS
2653	Total Knee Replacement: Average Change Between Pre-Operative and One Year (9 to 15 Months) Post-Operative Functional Status as Measured with the Oxford Knee Score	Outcome	Clinician	MNCM	
N/A	Total Knee Replacement: Average Change Between Pre-Operative and One Year (9 to 15 Months) Post-Operative Health-Related Quality of Life as Measured with the EQ-5D-5	Outcome	Clinician	MNCM	
N/A	Functional Status Change for Patients with Knee Impairments	Outcome	Clinician / Facility	FOTO	MIPS
N/A	Functional Status Change for Patients with Hip Impairments	Outcome	Clinician / Facility	FOTO	MIPS
1550	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	Outcome	Facility	CMS	CJR HIQR HVBP
1551	Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	Outcome	Facility	CMS	HIQR HRRP
IQI 14	Hip Replacement Mortality Rate	Outcome	Facility	AHRQ	
0354 IQI 19	Hip Fracture Mortality Rate	Outcome	Facility	AHRQ	
0351PSI 04	Death Rate Among Surgical Inpatients with Serious Treatable Complications	Outcome	Facility	AHRQ	HIQR
0753	Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	Outcome	Facility / Population	CDC / ACS	HAC-R HIQR
0697	Risk Adjusted Case Mix Adjusted Elderly Surgery Outcomes Measure	Outcome	Facility	ACS	
0299	Surgical Site Infection Rate	Outcome	Facility	CDC	
0450 PSI 12	Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate	Outcome	Facility	AHRQ	HIQR
0531 PSI 90	Patient Safety for Selected Indicators	Outcome	Facility	AHRQ	HAC-R
0166	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey Measure	Patient Experience	Facility	CMS	CJR HIQR HVBP
N/A	Unplanned Reoperation Within the 30-Day Postoperative Period	Outcome	Clinician / Facility	ACS	MIPS

Remaining Measurement Gaps Relevant to Hip and Knee Implants

Domain	Type	Level of Analysis	Gap
Treatment	Process	Clinician / Facility	Appropriate Surgical Intervention Selected Based on Patient Criteria
	Patient-Reported Outcome (PRO)	Clinician / Facility	Shared Decision-Making in Implant Selection
Monitoring	Process	Clinician	Use of Appropriate Imaging to Monitor Implant
	Process	Clinician / Facility	Timely Referrals for Post-Operative Physical Rehabilitation
Outcome	PRO	Clinician / Facility	Patient-Reported Change in Daily Living
	Outcome	Clinician / Facility	Risk-Adjusted Multi-Year Revision Rate
	Outcome	Clinician / Facility	Implant Failure Rate

Minimally Invasive Colectomy for Inflammatory Bowel Disease

Guidelines Assessed

Year	Organization	Title
2016	American Gastroenterological Association (AGA)	Crohn's Disease Clinical Care Pathway
		Ulcerative Colitis Clinical Care Pathway
		Management of Crohn's Disease After Surgery
2007	American Society of Colon and Rectal Surgeons (ASCRS)	Practice Parameters for the Surgical Management of Crohn's Disease
2005		Practice Parameters for the Surgical Treatment of Ulcerative Colitis
2005	Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)/ASCRS	Guidelines for Laparoscopic Colectomy Course

Clinical Recommendations

Guideline	Clinical Issue	Recommendation	Strength of Recommendation
ASCRS	Massive hemorrhage originating from any location	*Recommended.* Interventional radiologic or endoscopic techniques	Level III Grade B [Generally consistent findings from well-designed studies]
	Disease of colon requiring emergency or urgent surgery	*Recommended.* Subtotal or total colectomy with end ileostomy*	Level III Grade B [Generally consistent findings from well-designed studies]
	Disease of jejunum, proximal ileum, terminal ileum, or ileocolon without short-bowel syndrome	*Recommended.* Resection of affected bowel*	
	Emergency surgery in ulcerative colitis	*Recommended.* Subtotal or total colectomy with end ileostomy*	Grade 1B [Strong recommendation based on moderate-quality evidence]
	Elective surgery in ulcerative colitis	*Recommended.* Total proctocolectomy with ileostomy	
	Longstanding Crohn's disease with ileocolon or colon or ulcerative colitis	*Recommended.* Endoscopic surveillance	Level III Grade B [Generally consistent findings from well-designed studies] Grade 1B [Strong recommendation based on moderate-quality evidence]

* Minimally invasive surgery recommended equivalent to open surgery

Benefits of Minimally Invasive Colectomy

Benefit[65,66,67,68,69,71,72,171,172,173,174,175,176,177,178,179,180,181,182]
■ Shorter hospital stay
■ Shorter recovery time
■ Rapid resolution of postoperative ileus
■ Lower mortality rate
■ Lower surgical site infection rate
■ Lower complication/morbidity rate
■ Lower ostomy rate
■ Higher discharge rate
■ Lower cost
■ Less intraoperative blood
■ Reduced postoperative pain
■ Improved pulmonary function
■ Lower levels of inflammatory and stress response
■ Improved construction of subsequent pelvic pouch

IBD Measurement Opportunities

Domain	Type	Opportunity
Diagnosis	Process	Timely colonoscopy performed
	Process	Shared decision-making/diagnostic counseling performed
	Process	Risk assessment performed
Structural	Structural	Rate of minimally invasive colectomies performed at facility
Treatment	Process	Shared decision-making/treatment counseling performed
	Process	Timely initiation of steroid therapy
	Process	Timely initiation of anti-TNF therapy
	Process	Timely initiation of surgical intervention
Monitoring	Process	Colorectal cancer screening performed
	Process	Postoperative pharmacologic prophylaxis administered
Outcomes	Outcome	Rate of surgical mortality
	Outcome	Rate of complications following colectomy
	PRO	Patient-reported pain/quality of life
	Outcome	Hospital length of stay

Identified Quality Measures Relevant to Minimally Invasive Colectomy

ID	Measure Title	Type		Steward	Program Use
N/A	Inflammatory Bowel Disease (IBD): Type, Anatomic Location and Activity All Documented	Process	Clinician	AGA	
N/A	Anastomotic Leak Intervention	Process	Clinician	ACS	MIPS
0299*	Surgical Site Infection Rate	Outcome	Facility	CDC	
0753	Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	Outcome	Facility / Population	CDC	HAC-R HIQR HVBP
2687	Hospital Visits After Outpatient Surgery	Outcome	Facility	CMS	HOQR
2158	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	Outcome	Facility	CMS	HIQR HVBP MIPS
1789	Hospital Wide All-Cause Unplanned Readmission Measure	Outcome	Facility	CMS	HIQR MIPS MSSP
0706	Risk Adjusted Colon Surgery Outcome Measure	Outcome	Facility	ASC	
IQI 18	Gastrointestinal Hemorrhage Mortality Rate	Outcome	Facility	AHRQ	
PSI 04	Death Rate Among Surgical Inpatients with Serious Treatable Complications	Outcome	Facility	AHRQ	HIQR
PSI 25	Accidental Puncture or Laceration Rate	Outcome	Facility	AHRQ	HAC-R (Component of PSI 90 Composite)
PSI 90	Patient Safety and Adverse Events Composite	Outcome	Facility	AHRQ	HAC-R HIQR HVBP

* Endorsement Removed

Remaining Measurement Gaps

Domain	Type	Level of Analysis	Gap
Diagnosis	Process	Clinician / Facility	Risk Assessment Performed
Treatment	Process	Facility	Timely Initiation of Colectomy
Outcomes	Outcome	Facility	Anastomotic Leak Rate
	Outcome	Clinician / Facility	Patient-Reported Change in Quality of Life Following Colectomy
Structural	Structural	Facility	Monitoring Volume of MIS Colectomy at Facility

Negative Pressure Wound Therapy for Chronic Wound Care

Guidelines Assessed

Year	Organization	Title
2015	Wound Healing Society (WHS)	Chronic Wound Care Guidelines ■ Arterial Insufficiency Ulcers ■ Diabetic Ulcers ■ Pressure Ulcers ■ Venous Ulcers
2015	American College of Physicians	Treatment of Pressure Ulcers
2014	Society for Vascular Surgery (SVS) and the American Venous Forum	Management of Venous Leg Ulcers
2014	Wound, Ostomy and Continence Nurses Society (WOCN)	Guidelines for Management of Wounds ■ Lower-Extremity Arterial Disease
2012		■ Lower-Extremity Neuropathic Disease
2011		■ Lower-Extremity Venous Disease
2011	Emergency Nurses Association	Emergency Nursing Resource: Wound Preparation
2014	American College of Surgeons Committee on Trauma	An Evidence-Based Prehospital Guideline for External Hemorrhage Control
2007	Society of Thoracic Surgeons	Antibiotic Prophylaxis in Cardiac Surgery: Antibiotic Choice
2012	Academy of Nutrition and Dietetics	Critical Illness Evidence-Based Nutrition Practice Guideline
2011	American College of Cardiology Foundation / American Heart Association	Guideline for Coronary Artery Bypass Graft Surgery
2005		Guidelines for the Management of Patients with Peripheral Arterial Disease
2012	Hartford Institute for Geriatric Nursing	Comprehensive Assessment and Management of the Critically Ill
2016	Society for Vascular Surgery	Management of Diabetic Foot

Clinical Recommendations

Guideline	Clinical Issue	Recommendation	Strength of Recommendation
WOCNS	NPWT as adjunctive treatment for lower-extremity neuropathic disease	*Recommended.* Increases wound closure	Grade C [Low-quality evidence]
WOCNS	NPWT as adjunctive treatment for lower-extremity arterial disease	*Recommended.* For wounds with infected vascular grafts	Grade C [Low-quality evidence]
SVS	NPWT for chronic diabetic foot wounds	*Recommended.* For wounds that do not demonstrate expected healing progression after 4-8 weeks of therapy	Grade 2B [Mixed consensus, moderate-quality evidence]
WHS	NPWT for nonhealing diabetic wounds	*Recommended.* Consider use when other treatments are not effective	Level I [High-quality evidence]
WHS	NPWT for stage III or IV pressure ulcers	*Recommended.* For pressure ulcers that fail to progress in healing with conventional therapy	Level I [High-quality evidence]
WHS	NPWT for arterial ulcers	*Neutral Recommendation.* May have role as adjuvant agent, but further study is required	Level III C [Low-quality evidence]
WHS	NPWT for venous ulcers	*Neutral Recommendation.* Reported experience is limited	Level II [Moderate-quality evidence]
SVS/AVF	NPWT for venous leg ulcers	*Not recommended.* Not enough information to support primary use	Level C [Low-quality evidence]

Benefits of NPWT

Benefit[183,184,185,186,187,188,189,190]
■ Reduced time to healing
■ Higher percentage of healed wounds
■ Reduction in number of re-amputations
■ Reduced wound bed preparation time
■ Decreased wound size and depth
■ Reduced infection risk
■ Reduced number of dressing changes
■ Increased amount of granulation tissue
■ Higher uptake of skin graft

Chronic Wound Care Measurement Opportunities

Domain	Type	Opportunity
Diagnosis	Process	Patient Education Performed
	Process	Risk Screening Performed / Patient Medical History Collected
	Process	Nutritional Screening Performed
	Process	Appropriate Wound Care Specialist Referrals
Treatment	Process	Wound Debridement Performed
	Process	Appropriate Wound Dressings Provided
	Process	Appropriate Revascularization Performed
	Process	Initiate Appropriate Adjunctive Treatment (e.g., HBOT, NPWT)
Monitoring	Process	Smoking Cessation Counseling Provided
	Process	Appropriate Exercise Programs Implemented
	Process	Appropriate Foot Exams Conducted
	Process	Bacterial Burden Assessed
	Process	Patient Compliance with Adjunctive Therapy Assessed
Outcomes	Outcome	Rate of Wound Infection
	PRO	Patient-Reported Change in Wound Status (e.g., Depth, Size)
	Outcome	Rate of Amputation
	PRO	Patient-Reported Change in Pain

Identified Quality Measures Relevant to NPWT

ID	Measure Title	Type	Level of Analysis	Steward	Program Use
0538*	Pressure Ulcer Prevention and Care	Process	Facility	CMS	HHQR
N/A	Plan of Care Creation for Diabetic Foot Ulcer (DFU) Patients not Achieving 30% Closure at 4 Weeks	Process	Clinician / Facility	USWR	
N/A	Plan of Care for Venous Leg Ulcer Patients not Achieving 30% Closure at 4 Weeks	Process	Clinician / Facility	USWR	
N/A	Vascular Assessment of Patients With Chronic Leg Ulcers	Process	Clinician / Facility	USWR	
N/A	Wound Bed Preparation Through Debridement of Necrotic or Non-Viable Tissue	Process	Clinician / Facility	USWR	
N/A	Patient Reported Experience of Care: Wound Related Quality of Life	Process	Clinician / Facility	USWR	
N/A	Patient Reported Experience of Care: Wound Outcome	Process	Clinician / Facility	USWR	
N/A	Nutritional Screening and Intervention Plan in Patients with Chronic Wounds and Ulcers	Process	Clinician / Facility	USWR	
0181*	Increase in Number of Pressure Ulcers	Outcome	Clinician / Facility	CMS	HHQR
0201*	Pressure Ulcer Prevalence (Hospital Acquired)	Outcome	Clinician / Facility	Joint Commission	
0198*	High-Risk Resident with Pressure Ulcers	Outcome	Facility	CMS	
0199*	Average-Risk Residents with Pressure Ulcers	Outcome	Facility	CMS	
0337	Pressure Ulcer Rate (PDI 2)	Outcome	Facility	AHRQ	
0679	Percent of High-Risk Residents with Pressure Ulcers (Long Stay)	Outcome	Facility	CMS	NHQI
0678	Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short Stay)	Outcome	Facility	CMS	HHQR LTCHQR NHQI SNFQR
N/A	Percent of Residents or Patients with Pressure Ulcers that are New or Worsened	Outcome	Facility	CMS	HHQR
0178	Improvement in Status of Surgical Wounds	Outcome	Facility	CMS	HHQR
N/A	Diabetic Foot Ulcer (DFU) Healing or Closure	Outcome	Clinician / Facility	USWR	
N/A	Venous Leg Ulcer Outcome Measure: Healing or Closure	Outcome	Clinician / Facility	USWR	
N/A	Lower-Extremity Amputation Among Patients with Diabetes	Outcome	Facility	AHRQ	

* NQF endorsement removed

Remaining Measurement Gaps Relevant to NPWT

Domain	Type	Level of Analysis	Gap
Diagnosis	Process	Clinician	Risk Screening Used in Care Planning Discussions
Treatment	Process	Clinician	Appropriate and Timely Use of NPWT
Monitoring	Process	Clinician	Bacterial Burden Assessed
	Process	Clinician	Patient Compliance with Adjunctive Wound Therapies Assessed
Outcomes	Outcome	Clinician / Facility	Chronic Wound Infection Rate
	Outcome	Clinician / Facility	Patient Reported Change in Chronic Wound Status
	Outcome	Facility	Re-Amputation Among Patients with Diabetes

Prothrombin International Normalized Ratio Home Testing for Pulmonary Embolism

Guidelines Assessed

Year	Organization	Title
2016	American College of Chest Physicians (ACCP)	Evidence-Based Management of Anticoagulant Therapy
2013	American Academy of Family Physicians (AAFP)	Updated Guidelines on Outpatient Anticoagulation
2007		Current Diagnosis of Venous Thromboembolism in Primary Care
2004		DVT and Pulmonary Embolism
2008	Anticoagulation Forum	Delivery of Optimized Anticoagulant Therapy: Consensus Statement
2015	American College of Physicians (ACP)	Evaluation of Patients with Suspected Acute Pulmonary Embolism
2011	American Heart Association (AHA)	Management of Massive and Submassive Pulmonary Embolism, Iliofemoral Deep Vein Thrombosis, and Chronic Thromboembolic Pulmonary Hypertension
2011	American College of Emergency Physicians (ACEP)	Critical Issues in the Evaluation and Management of Adult Patients Presenting to the ED with Suspected Pulmonary Embolism
2005	International Self-Monitoring Association for Oral Anticoagulation (ISMAAP)	Guidelines for Implementation of Patient Self-Testing and Patient Self-Management of Oral Anticoagulation

Clinical Recommendations

Guideline	Clinical Issue	Recommendation	Strength of Recommendation
ACCP	Patients on vitamin K antagonist (VKA) therapy	*Recommended*. Those treated with VKA who are motivated and competent should use patient self-management	Class 2B [weak recommendation, moderate-quality evidence]
AAFP	INR self-testing	*Recommended*. Point-of-care monitors can be used in home settings for some patients to check their INRs at home	Level A [Consistent, good-quality patient-oriented evidence]
ACF	Prothrombin time testing	*Recommended*. Should be performed on either plasma samples in a clinical laboratory or whole blood capillary (finger stick) samples utilizing point-of-care devices	Not specified

Benefits of PT INR Home Testing

Benefit[191,192,193,194,195,196,197,198,199,200,201,202,203]
■ Reduced mortality ■ Reduced thromboembolic events ■ Reduced thrombotic events ■ Improved INR TTR ■ Improved patient satisfaction ■ Reduced major hemorrhage ■ Accurate testing ■ Reduced complications ■ Reduced cost

Pulmonary Embolism Measurement Opportunities

Domain	Type	Opportunity
Diagnosis	Process	Risk Scoring Performed
	Process	D-dimer or CT Testing Performed
	Process	Timeliness of Risk Stratification / Testing Upon Admission
Treatment	Process	Timely Initiation of Anticoagulant / Warfarin Therapy
	Process	Timely Initiation of Catheter-Directed Thrombolysis
	Process	Timely Implantation of Inferior Vena Cava Filter
	Process	Timely Initiation of Endarterectomy
Monitoring	Process	Timely Initiation of Supportive Therapy
	Process	Prescribing PT INR Home Monitoring for Self-Management
Outcomes	Outcome	Rate of Post-Treatment Complications
	Outcome	Time in Therapeutic Range (TTR)
	Outcome	Rate of Mortality
Structural	Structural	Device Competency Tested
	Structural	Collection of Device-Reported Patient Data

Identified Quality Measures Relevant to PT INR Home Testing

ID	Measure Title	Type	Level of Analysis	Steward	Program Use
0555	INR Monitoring for Individuals on Warfarin	Process	Clinician / Health Plan / Population	CMS	
0556	INR for Individuals Taking Warfarin and Interacting Anti-Infective Medication	Process	Health Plan / Population	CMS	
0586*	Warfarin PT/INR Test	Process	Clinician / Health Plan / Population	Resolution Health, Inc.	
0612*	Warfarin – INR Monitoring	Process	Clinician / Facility / Health Plan / Population	ActiveHealth Management	
2732	INR Monitoring for Individuals on Warfarin after Hospital Discharge	Process	Facility	CMS	
N/A	Percentage of Hospitalized Patients on Warfarin for Whom Current International Normalized Ratio is Used to Monitor and Adjust Therapy	Process	Facility	ICSI	
0531 PSI90	Patient Safety for Selected Indicators (Composite Measure)	Outcome	Facility	AHRQ	HIQR HVBP HAC-R
0351 PSI4	Death Among Surgical Inpatients With Serious, Treatable Complications	Outcome	Facility	AHRQ	HIQR
0697	Risk Adjusted Case Mix Adjusted Elderly Surgery Outcomes Measure	Outcome	Facility	ACS	
N/A	Percent of Time in Therapeutic INR Range (TTR): Mean TTR Achieved Among Patients Who Received Prescriptions for Warfarin and Had Sufficient INR Values to Calculate TTR	Outcome	Facility	USVA	
IA PM 2	Anticoagulant Management Improvements	Improvement Activity	Clinician	CMS	MIPS
IA PM 1	Participation in Systematic Anticoagulation Program	Improvement Activity	Clinician	CMS	MIPS

* Endorsement Removed

Remaining Measurement Gaps Relevant to PT INR Home Testing

Domain	Type	Level of Analysis	Gap
Monitoring	Process	Clinician / Facility	Home PT INR Testing Prescribed for Self-Management
Outcomes	Outcome	Clinician / Facility	Percentage of Critical INR Values
	Outcome	Clinician / Facility	INR Variability (Percentage of INRs Within Range)
	Outcome	Clinician / Facility	TTR + Standardized INR Variability
	Outcome	Facility	Acute Thromboembolic Event Rate
	Outcome	Facility	Rate of Emergency Room or Inpatient Admissions for Bleeding Events
Structural	Structural	Clinician / Facility	Use of Certified EHR to Collect Device-Reported Data
	Structural	Clinician / Facility	Comparison of Lab and Home Device Values

Stereotactic Body Radiation Therapy for Non-Small Cell Lung Cancer

Guidelines Assessed

Year	Organization	Title
2016	National Comprehensive Cancer Network (NCCN)	Clinical Practice Guidelines in Oncology ■ Non-Small Cell Lung Cancer ■ Small Cell Lung Cancer
2015	American Society for Radiation Oncology (ASTRO)	Definitive Radiation Therapy in Locally Advanced Non-Small Cell Lung Cancer
2015	American Society of Clinical Oncology (ASCO)	Definitive and Adjuvant Radiotherapy in Locally Advanced Non-Small-Cell Lung Cancer
2007		Adjuvant Chemotherapy and Adjuvant Radiation Therapy for Stages I-IIIA Resectable Non-Small-Cell Lung Cancer Guideline

Clinical Recommendations

Guideline	Clinical Issue	Recommendation	Strength of Recommendation
NCCN	SBRT for NSCLC	*Recommended.* Use for Stage IA, medically inoperable patients, node negative Stage IIA	Uniform NCCN consensus that intervention is appropriate [Category 2A]
ASCO	SBRT for Locally Advanced NSCLC	*Recommended.* Use for patients ineligible for combined modality treatment	Strong recommendation, high-quality evidence
ASTRO	SBRT for Locally Advanced NSCLC	*Recommended.* Radiation therapy alone is superior to observation strategies or chemotherapy alone	Strong recommendation, moderate-quality evidence
	SBRT for Locally Advanced NSCLC Ineligible for Combined Modality Therapy	*Recommended.* Use radiation therapy alone	Strong recommendation, high- quality evidence

Benefits of SBRT

Benefit[100,204,205,206,207,208,209,210,211,212,213]
■ Improved treatment accuracy
■ Reduction of safety margins
■ 3- and 5-year local tumor control rate / Improved local control
■ Reduced treatment-related death
■ Limited toxicity
■ Fewer grade 4 events
■ Improved progression rates
■ Improved survival
■ Higher patient satisfaction

NSCLC Measurement Opportunities

Domain	Type	Opportunity
Diagnosis	Process	Timely diagnostic imaging
	Process	Timely biopsy
	Process	Timely imaging and biopsy for staging
	Process	Cancer staging
	Process	Use of surgical and radiation oncology referrals
Structure	Structure	Implementation of multidisciplinary care team
Treatment	Process	Timely initiation of surgery
	Process	Timely initiation of definitive RT in medically inoperable patients
	Process	Timely initiation/dosing of chemotherapy or chemoradiation
	Process	Safe levels of SBRT dosing
Monitoring	Process	Smoking cessation counseling
	Process	Timely imaging
	Process	Patient experience survey
Outcome	Outcome	Survival rate (overall, disease-free)
	Outcome	Disease recurrence rate
	Outcome	Quality of life (fatigue, dyspnea, pain)

Identified Quality Measures Relevant to SBRT

ID	Measure Title	Type	Level of Analysis	Steward	Program Use
N/A	Pathology: Percentage of Pathology Reports for Primary Lung Carcinoma Resection Specimens That Include the pT Category, pN Category and for Non-Small Cell Lung Cancer, Histologic Type	Process	Clinician	College of American Pathology (CAP)	
N/A	Pathology: Percentage of Biopsy and Cytology Specimen Reports With a Diagnosis of Non-Small Cell Lung Cancer That Are Classified into Specific Histologic Type or Classified as NSCLC-NOS With an Explanation Included in the Pathology Report	Process	Clinician	CAP	
0455	Recording of Clinical Stage Prior to Surgery for Lung Cancer or Esophageal Cancer Resection	Process	Clinician / Facility	Society for Thoracic Surgeons (STS)	MIPS PQRS
10RLN	At Least 10 Regional Lymph Nodes are Removed and Pathologically Examined for AJCC Stage IA, IB, IIA, and IIB Resected NSCLC	Process	Clinician	American College of Surgeons (ACS)	
0382	Oncology: Radiation Dose Limits to Normal Tissues	Process	Clinician	American Society for Radiation Oncology (ASTRO)	MIPS PCHQR PQRS
N/A LNoSurg	Oncology: Percentage of Patients, Regardless of Age, With a Diagnosis of Breast, Rectal, Pancreatic or Lung Cancer Receiving 3D Conformal Radiation Therapy Who had Documentation in Medical Record that Radiation Dose Limits to Normal Tissues Were Established Prior to the Initiation of a Course of 3D Conformal Radiation for a Minimum of Two Tissues	Process	Clinician	ASTRO	
	Surgery Is Not the First Course of Treatment for cN2, M0 Lung Cases	Process	Clinician	ACS	
0384	Oncology: Medical and Radiation – Pain Intensity Quantified	Process	Clinician	PCPI®	MIPS MU-EP OCM PCHQR PQRS

ID	Measure Title	Type	Level of Analysis	Steward	Program Use
0383	Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology	Process	Clinician	PCPI®	MIPS OCM PCHQR PQRS
N/A	Risk-Adjusted Proportion of Patients With All-Cause Hospital Admissions Within the 6-Month Episode	Outcome	Facility	Centers for Medicare & Medicaid Services (CMS)	OCM
N/A	Risk-Adjusted Proportion of Patients with All-Cause ED Visits That Did Not Result in a Hospital Admission Within the 6-Month Episode	Outcome	Facility	CMS	OCM
N/A	Proportion of Patients Who Died Who Were Admitted to Hospice for 3 Days or More	Outcome	Facility	CMS	OCM

Remaining Measurement Gaps Relevant to SBRT

Domain	Type	Level of Analysis	Gap
Assessment	Structure	Facility / Health Plan	Use of Multidisciplinary Team in Early Stage NSCLC Evaluation
	Process	Facility / Health Plan	Early Stage NSCLC Patients Referred to Radiation Oncologist
Treatment	Process	Clinician	Medically Inoperable Patients (Stage I-II T1-3, N0, M0, or High-Risk Refusing Surgery) Receiving SABR/SBRT
	Process	Clinician	Appropriate RT Dosing for Patients Receiving SABR/SBRT
Outcome	Outcome	Facility	Risk-Adjusted NSCLC Recurrence Rate
	Outcome	Facility	Risk-Adjusted NSCLC Survival Rate
	Patient-Reported Outcome (PRO)	Facility / Health Plan	Patient Satisfaction with Shared Decision-Making regarding Access to Radiation Oncologists

Telehealth and Remote Patient Monitoring for Heart Failure

Guidelines Assessed

Year	Organization	Title
2013	American College of Cardiology Foundation (ACCF) / American Heart Association (AHA)	Management of Heart Failure
2015	Heart Rhythm Society (HRS)	Remote Interrogation (RI) and Monitoring (RM) for Cardiovascular Implantable Electronic Devices (CIEDs)
2016	European Society of Cardiology (ESC)	Guidelines for the Diagnosis and Treatment of Acute and Chronic Heart Failure
2016	ACCF / AHA / Heart Failure Society of America (HFSA)	Pharmacological Therapy for Heart Failure
2009	HFSA	Genetic Evaluation of Cardiomyopathy
2010		Comprehensive Heart Failure Practice Guideline
2014	State Medical Boards' Appropriate Regulation of Telemedicine (SMART) Workgroup	Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine
2014	American Telemedicine Association	Practice Guidelines for Live, On Demand Primary and Urgent Care
2014		Guidelines for TeleICU Operations
2011		Videoconferencing-Based Telepresenting

Clinical Recommendations

Guideline	Clinical Issue	Recommendation	Strength of Recommendation
HRS	CIED monitoring and interrogation, with annual in-person evaluation	*Recommended*. Recommended over calendar-based schedule of in-person evaluation alone	Class IA [Treatment is useful / effective with sufficient evidence from multiple RCTs or meta analyses]
	Remote monitoring for CIED	*Recommended*. Recommended as part of standard follow-up management	
	RM for thoracic impedance or for management of congestive heart failure	*No Recommendation*. The effectiveness of RM is currently uncertain	Class IIbC
ESC	Monitoring of pulmonary artery pressures using wireless implantable hemodynamic monitoring systems	*Recommended*. Should be considered in symptomatic patients with HF with previous hospitalization	Class IIb Level B
	Multiparameter monitoring based on ICD	*Recommended*. May be considered in symptomatic patients with heart failure with reduced ejection fraction	Class IIb Level B
ACCF / AHA	Use of systems of care to promote care coordination for patients with chronic HF (including remote telemonitoring programs)	*No Recommendation*. Based on the quality of evidence	None specified ["Quality of evidence is mixed for specific HF interventions"]

Benefits of Telehealth and RPM

Benefit[117,214,215,216,217,218,219,220,221,222,223,224,225,226,227,228,229,230,231,232,233,234,235,236,237,238]
■ Reduced all-cause death
■ Reduced HF hospital admissions
■ Change in New York Hospital Association (NYHA) class
■ Change in patient global self-assessment
■ Reduced device- or system-related complications
■ Improved HF deterioration detection
■ Reduced mortality rate
■ Improved health-related quality of life
■ Improved survival
■ Reduced mean daily left atrial pressure
■ Improved identification of HF hospitalization risk
■ Reduced cardiac death
■ Reduced hospital length of stay
■ Lowered direct costs
■ Reduced rehospitalization
■ Reduced cases of multiple readmissions
■ Improved time to clinical decision

Heart Failure Measurement Opportunities

Domain	Type	Opportunity
Diagnosis	Process	Physical Examination and Assessment Conducted
	Process	Appropriate Testing Conducted
	Process	Risk Scoring Assessment Conducted
Treatment	Process	Appropriate Prescribing ACE Inhibitor or ARB Medication
	Process	Appropriate Prescribing Beta-Blockers
	Process	Appropriate Prescribing Statins
	Process	Appropriate Initiation of Surgical Procedures (Revascularization, ICD, CRT, Transplant)
Monitoring	Process	Post-Treatment Assessment
	Process	Implementation of Self-Care Education
	Process	Appropriate Initiation of Remote Monitoring
Outcome	Outcome	Heart Failure Complication Rate
	PRO	Patient-Reported Change in Quality of Life
	Outcome	Heart Failure Admission Rate
	Outcome	Heart Failure Readmission Rate
	Outcome	Heart Failure Mortality Rate
Structural	Structural	Collection of Device-Reported Heart Failure Data

Identified Quality Measures Relevant to Telehealth and RPM

ID	Measure Title	Type	Level of Analysis	Steward	Program Use
0521*	Heart Failure Symptoms Addressed	Process	Facility	CMS	HHQR
0077*	Heart Failure (HF): Assessment of Activity Level	Process	Clinician	AMA-PCPI	
0078*	Heart Failure (HF): Assessment of Clinical Symptoms of Volume Overload (Excess)	Process	Clinician	AMA-PCPI	
0079	Heart Failure: Left Ventricular Ejection Fraction Assessment (Outpatient Setting)	Process	Clinician	AHA / ASA	
0085*	Heart Failure (HF): Weight Measurement	Process	Clinician	AMA-PCPI	
0135*	Evaluation of Left Ventricular Systolic Function (LVS)	Process	Facility	CMS	HIQR
2450	Heart Failure: Symptom and Activity Assessment	Process	Clinician	ACC	
2461	In-Person Evaluation Following Implantation of a Cardiovascular Implantable Electronic Device (CIED)	Process	Clinician	HRS	
0277	Heart Failure Admission Rate (PQI 8)	Outcome	Health Plan	AHRQ	
0330	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization	Outcome	Facility	CMS	HIQR HRRP
1789	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	Outcome	Facility	CMS	HIQR MSSP
0229	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization for Patients 18 and Older	Outcome	Facility	CMS	HIQR HVBP
0358	Heart Failure Mortality Rate (IQI 16)	Outcome	Facility	CMS	
2483	Gains in Patient Activation (PAM) Scores at 12 Months	Outcome	Clinician	Insignia Health	
IA EPA 2	Use of Telehealth Services that Expand Practice Access	Improvement Activity	Clinician	CMS	MIPS

* Endorsement Removed

Remaining Measurement Gaps Relevant to Telehealth and RPM

Domain	Type	Level of Analysis	Gap
Treatment	Process	Clinician	Patient Education Provided for Remote Patient Monitoring
Monitoring	Process	Clinician	Flagged Telemonitoring Notifications Resulting in Change in Treatment
Outcome	PRO	Clinician	Change in Patient-Reported Heart Failure Quality of Life
Structural	Structural	Facility	Rate of Enrollment in Remote Patient Telehealth Monitoring Service for Chronically Ill Patients
	Structural	Facility	Rate of Activation of RPM Services for Eligible Patients with CIED

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