Quality Measure Concepts to Fill Gaps in Oral Oncolytic Adherence:
A Multi-Stakeholder Workgroup-Identified Measurement Strategy

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A multi-stakeholder workgroup of oncology and quality measurement experts explored gaps in quality measures focused on oral oncolytic adherence and identified priority measure concepts and needed action steps to advance them.

BACKGROUND

- Oral oncolytics have changed the way care teams and their patients manage cancer care
- Oral oncolytics offer many advantages over traditional intravenous (IV) infusions, including greater flexibility and home-based treatments that limit disruptions to patients' daily lives[1,2,3]
- Conversely, at-home treatments may lead to increased nonadherence given the greater reliance on self-management[4]
- In the US, approximately 50% of medications are taken incorrectly, and medication nonadherence contributes to 125,000 deaths each year[5,6]
- Nonadherence is directly associated with increased physician visits, higher hospitalization rates, longer hospital stays, worsening disease, and increased mortality, as well as $100-300 billion in US healthcare costs annually[5,4]
- Adherence rates for cancer therapy range from 15%-97%[4]
- Numerous factors impact adherence to treatment **(Figure 1)**
- Quality measures are tools utilized for quality improvement and accountability.[7] Medication adherence quality measures have been used for other medication types to monitor adherence **(Table 1)**, but none exists for oral oncolytic therapies
- Given variation in adherence and the impact on clinical and cost outcomes, cancer adherence quality measures should be prioritized

FIGURE 1. FACTORS IMPACTING ADHERENCE

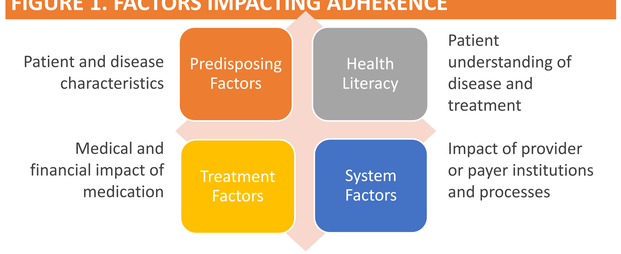


TABLE 1. IDENTIFIED QUALITY MEASURES AND GAPS

Category		Example Identified Measures	Potential Measure Gaps
Factors Impacting Adherence	Predisposing Factors	Screening for Depression and Follow-Up Plan (Centers for Medicare & Medicaid Services)	Screening measures for medication access challenges
	Health Literacy	Oral Chemotherapy Education Provided Prior to the Start of Therapy (American Society of Clinical Oncology)	Measures assessing change in patient knowledge or understanding
	Treatment Factors	Oncology: Patient-Reported Pain Improvement (McKesson)	Measures assessing oral oncolytic adverse events and management
	System Factors	Goal Setting and Attainment for Cancer Survivors (Oncology Nursing Society)	Prescription adjudication and dispensing measures
Monitoring Adherence Rate		Early Persistence to Oral Oncolytics (Pharmacy Quality Alliance – Measure Concept only)	Persistence, medication possession ratio, or proportion of days covered measures

OBJECTIVES

1. Engage oncology stakeholders and adherence measurement experts to advance development of quality measures to drive oral oncolytic adherence, including novel approaches to assessing adherence rates and measures assessing factors that impact adherence
2. Define barriers and opportunities to specifying and testing measures for oral oncolytic adherence
3. Identify a package of 1-3 measure concepts that will advance measurement of oral oncolytic adherence, prioritized by both impact and feasibility
4. Identify action steps for developing prioritized measure concepts

METHODS

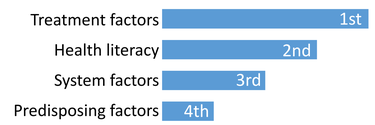
- Convened multi-stakeholder workgroup: providers, patient advocates, pharmacists, payers, researchers, measure developers, and vendors
- Facilitated virtual collaborative sessions **(Figure 2)**
- Used facilitated discussion and polling to identify participant rankings of 1) factors impacting adherence, 2) the ability for providers to impact those factors, and 3) the priority adherence measure gaps for conceptualization **(Figure 3)**
- Used dot voting to identify and prioritize measure concepts for 1) measuring factors impacting adherence, and 2) measuring adherence rates **(Table 2)**
- Used facilitated discussion and online whiteboarding to draft and refine measure concepts for *Screening for Med Access Challenges, Patient - Provider Communication,* and *Assessment of Adherence Rate* **(Figure 4)**

FIGURE 2. WORKGROUP SESSION RESULTS

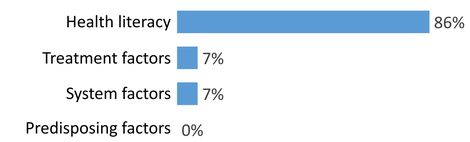
Factors Impacting Adherence	Adherence Rate
Session 1: Prioritize performance and measure gaps	
Priority Gap: Screening for **perceived** need and help seeking **Priority Gap**: Shared decision-making for therapy selection **Priority Gap**: Screening for medication access challenges	**Priority Gap**: Assessment of adherence rate
Session 2: Brainstorm concepts for prioritized measure gaps	
Concept: Screen for access barriers at point of prescribing and referral to support **Concept:** Patient-provider communication of adherence risks for treatment, decision-making, and maintenance	Concept not prioritized during Session 2
Session 3: Refine concepts based on data availability and prioritize feasibility challenges to address	
Refined Concept: Documentation of screening and referral in medical record or electronic medical record (EMR) **Refined Concept:** Bi-directional communication at time of prescribing and subsequent follow-up	**Concept Discussed**: Persistence/discontinuation rate or novel measurement approach preferred over medication possession ratio (MPR)/proportion of days covered (PDC)
Session 4: Consider measure use and usability and identify action steps	
Identified Action Step: Identify best practices and screening tool **Identified Action Step:** Demonstrate impact on outcomes	**Identified Action Step:** Close clinical – pharmacy interoperability gap **Identified Action Step:** Identify subpopulation for testing concept
Session 5: Finalize consensus-based action steps for furthering measure package	

FIGURE 3. SESSION 1 ADHERENCE FACTORS POLLING (A,B,C)

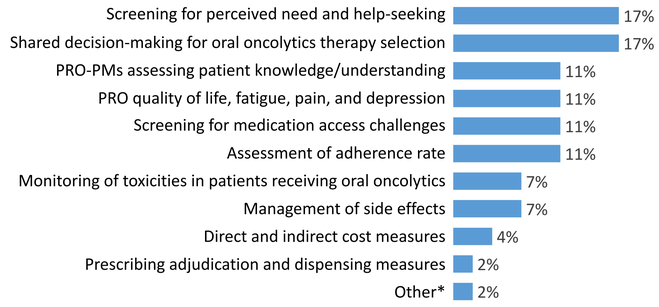
A. Workgroup ranking of factors impacting adherence by importance:



B. Workgroup ranking of factors impacting adherence by provider ability to impact change:



C. Workgroup prioritization of measure gaps for conceptualization:



**Focus on Patient Reported Outcome-Performance Measures (PRO-PMs) assessing challenges to accessing medication and navigating barriers to care*

TABLE 2. SESSION 2 MEASURE GAP DOT VOTING RESULTS

Group	Screening for Perceived Need and Help-Seeking	Shared Decision Making/ Provider Communication	Screening for Medication Access Challenges	Assessment of Adherence Rate
Group A	3	5	12	10
Group B	2	13	11	10
Group C	9	10	5	6

About Table 2:
- The multi-stakeholder workgroup was split into three groups: A, B, C
- Each person had three differently weighted votes: 1,2, and 3 points
- Prioritized gaps were identified in the exercise, and then the workgroup proposed concepts to close these gaps

FIGURE 4. PRIORITIZED MEASURE CONCEPT PACKAGE

Factors Impacting Adherence		Adherence Rate
Screening for Med Access Challenges	**Patient - Provider Communication**	**Assessment of Adherence Rate**
Measure concept: Documentation of screening and referral in medical record or EMR	**Measure concept:** Bi-directional patient and provider communication at time of prescribing and subsequent follow-up	**Measure concept:** Persistence/ discontinuation rate, or novel measurement approach (preferred over MPR / PDC)

RESULTS

- The workgroup prioritized gaps in performance and measurement, brainstormed and refined three measure concepts in two focus areas, discussed data feasibility challenges, and advised on action steps to advance future development of the identified concepts
- **Factors Impacting Adherence:** The workgroup identified measure concepts for screening for medication access challenges and patient-provider communication
  - **Screening for Medication Access Challenges**
    - Screening for medication access challenges before prescribing oral oncolytics, and throughout treatment, is a key step to addressing multiple factors impacting adherence
  - **Patient-Provider Communication**
    - Bi-directional exchange of information between patients, caregivers, and the full care team is vital to ensuring patients and caregivers understand treatment options and accompanying risks, and providers understand threats to adherence so that they are positioned to manage them throughout the patient's journey
- **Adherence Rate:** The workgroup further prioritized measure concepts to monitor adherence rates for oral oncolytics
  - The current common methods for assessing adherence, mainly medication possession ration (MPR) and proportion of days covered (PDC), may not be the right approach for oral oncolytics given unique challenges to cancer care
  - As an alternative, the group proposed persistence rates or discontinuation rates to assess adherence
- The workgroup identified current barriers **(Table 3)** and critical action steps to advance recommended oral oncolytic adherence measure concepts **(Table 4)**
- One common concern among the workgroup was that medication access screening considerations and patient-provider information exchange need to occur at ongoing points in the care journey, not just before or at the time of prescription
- The workgroup agreed that a multidisciplinary approach is crucial to managing care for patients taking oral oncolytics
- "Care Team" refers to all members of the care team supporting a patient and their caregivers (e.g., prescribing oncologist, oncology nurses, patient/care navigators, pharmacists)

TABLE 3. BARRIERS

Category	Identified Barriers Impacting Measure Development
Factors Impacting Adherence	Best practices or standards for screening and follow-up have not been identified
	Standardized screening tools, checklists, and patient-reported surveys have not been developed
	Data capture process for medication access barriers are not integrated into current workflows/EMR systems
Monitoring Adherence Rate	Evidence gaps (e.g., permissible gap days by drug class, priority outcomes for oncolytic adherence, and defined patient characteristics for performance adjustment) persist
	Clinical and pharmacy data necessary for identifying cancer patient denominators are not integrated

TABLE 4. PROPOSED ACTION STEPS

Step	Identified Action Steps to Advance Measurement
1	Identify and establish best practices to screen patients for medication access challenges
2	Develop and validate a standardized screening tool for medication access challenges
3	Support integration of medication access challenge screening into routine workflow and electronic data collection
4	Identify and establish best practices for care teams to communicate with patients and caregivers about oral oncolytic therapy and risk factors for nonadherence (e.g., financial/insurance considerations, side effects)
5	Determine if existing patient-reported measures (including patient-reported outcome measures (PROMs) and patient experience surveys) can be leveraged to support data collection for future measures assessing bi-directional communication about oral oncolytic treatment, or if new patient-reported measures should be developed and validated
6	Close evidence gaps relevant to clinical characteristics for risk adjustments and impact of adherence on outcomes
7	Identify and integrate clinical and pharmacy data elements (prescription claims or other pharmacy metrics) into routine data collection required for adherence measurement

CONCLUSIONS

- Impediments to oral oncolytic adherence, including disease characteristics, health literacy, and treatment and system factors, as well as variation in rates of adherence, demonstrate the need for quality measures
- A multi-stakeholder workgroup consisting of cancer care and measurement experts prioritized gaps in oral oncolytic adherence performance measures, identified and refined a package of measure concepts that should be prioritized for further exploration, and advised on necessary action steps to advance future development of the identified concepts
- Ultimately, this research highlights gaps in the oral oncolytics adherence quality measure landscape and prioritizes areas for further development with potentially large impacts on patients and US health care
- Advancing these workgroup recommendations will require collaboration across a spectrum of oncology, pharmacy, policy, and health IT stakeholders

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