PQA

RECOMMENDATIONS TO IMPROVE THE QUALITY OF ORAL ANTICANCER MEDICATION USE

A report from the PQA Quality Innovation and Research Initiative for Oncology

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EXECUTIVE SUMMARY

A health plan performance measure to assess the degree to which patients take their oral anticancer medications (OAM) as prescribed is the number one measurement priority according to 23 national experts and patients convened by the Pharmacy Quality Alliance (PQA).

This could be measured by adherence or persistence, but the uniqueness of OAMs – including complex treatment regimens, variable dosing schedules, and temporary and intentional discontinuation of therapy – present distinct challenges to accurately defining and measuring adherence and persistence.

PQA will use its research and measurement expertise to explore novel methods to inform potential development of an OAM adherence or persistence health plan measure. Adherence is commonly defined as the proportion of days in which a person has access to a medication over a given period of interest, and persistence is generally defined as not having a significant lapse in therapy.

Reaching consensus on an OAM measurement priority that can be pursued in the short term beginning with methodological research is a major accomplishment, given the difficulty of developing feasible and usable measures for this important and growing area of patient care.

An Initiative to Improve the Quality of OAM Use

The use of OAMs has increased significantly in recent years. There were at least 122 FDA-approved OAMs used in clinical practice in 2022. The quality of OAM use impacts clinical care, care coordination, patient safety and outcomes, including disparities in care, patient and caregiver experience, population health and prevention, and total health care costs.

To help improve the quality of care for individuals using OAMs, PQA created a "Quality Innovation and Research Initiative for Oncology." Work on this initiative began in 2022 to identify research and measurement opportunities aimed at assessing the quality of OAM use.

PQA invited patients with lived experience, OAM experts, and stakeholders from pharmacies, health plans, health care providers, biopharmaceutical companies, associations and academia to participate in three *PQA Convenes* workshops between late 2022 and early 2023. The discussions were informed by an expansive environmental scan conducted by PQA to identify OAM quality gaps and existing measures relevant to OAM care. The scan identified eight quality issues related to OAM use, and a lack of relevant OAM-related quality measures for health plan and pharmacy performance assessment.

A health plan performance measure to assess the degree to which patients take their oral anticancer medications (OAM) as prescribed is the number one measurement priority according to 23 national experts and patients convened by the Pharmacy Quality Alliance (PQA).

The evaluation of measure concepts during the workshops was framed by standard measure criteria, which include measure importance, scientific acceptability, feasibility, and usability. These criteria are critical for identifying and vetting measure concepts that can be successfully developed and effectively used in real-world settings.

The health plan measure concept for adherence or persistence to OAMs was rated highest among workshop advisors. To advance this concept, PQA will:

- Compile available measure specifications for metrics currently used by organizations for internal assessments of adherence or persistence to OAMs.
- Identify methodologies to assess OAM adherence and persistence that may be appropriate for health plan performance measurement.
- Conduct initial feasibility and validity assessments of prioritized adherence or persistence methodologies.

A separate measure concept of time-to-treatment was the top priority for pharmacy measurement. However, this concept significantly overlaps with the PQA-endorsed *Specialty Pharmacy Turnaround Time* (SP-TAT) pharmacy measure and a PQA pharmacy measure concept in development, *Specialty Pharmacy Prescription Abandonment Rate*. Additionally, time-to-treatment not captured in those two measures is largely outside of a pharmacy's control, which is essential for appropriate attribution and fair measurement. PQA encourages the industry to use or pilot these existing measures to help clarify the degree to which they assess timely access to OAMs.

This OAM quality initiative is led by the PQA Quality Innovation and Research Center (QuIRC), a strategic initiative to accelerate progress in medication use quality and focus on clinical outcomes and provider contributions to care. QuIRC brings together the data, infrastructure and resources needed to develop new, complex quality measures; support their implementation; and create tools and solutions for improving medication use and medication management services. QuIRC is ideal for answering the methodology questions needed to advance the prioritized health plan measure concept for adherence or persistence to OAMs.

Through QuIRC, PQA will begin research to advance the health plan measure concept for adherence or persistence to OAMs in 2024.

INTRODUCTION

The number and use of oral anticancer medications (OAMs) has grown dramatically over the last 20 years, with at least 122 OAMs approved by the U.S. Food and Drug Administration used in clinical practice in 2022.[2] The expansion of OAMs introduced new and unique challenges to cancer management. For example, patients on OAMs assume the primary responsibility of managing their medications at home, unlike parenteral therapy, which is administered under the supervision of a health care team in a health center. Patients have reported preferences for OAMs related to the perception of increased convenience, improved self-determination and autonomy, improved comfort due to the ability to stay at home during treatment, and the ability to continue working during treatment.[3] Additionally, many patients prefer the flexibility to avoid needles, especially individuals with a prior history of difficult intravenous access, fear of needles, general anxiety for parenteral treatment, or a preference for oral medications.[3]

The care provided to individuals with a cancer diagnosis is complex, requiring a team-based approach. Each member of the care team, within and across settings, plays a role in influencing and supporting patients to achieve their care goals. It may therefore be difficult to attribute the quality of care provided to individuals being treated for cancer to a single provider or entity due to this complexity and multidisciplinary care.[4] Further complicating the issue is that care tends to be fragmented, underscoring the challenge to determine provider-specific responsibility for a desired outcome.[5]

The quality of OAM use impacts clinical care, care coordination, patient safety and outcomes, including disparities in care, patient and caregiver experience, population health and prevention, and total health care costs.

Recognizing the growing availability and demand for OAMs combined with the complex and multidisciplinary nature of cancer treatment, the Pharmacy Quality Alliance (PQA) created a "Quality Innovation and Research Initiative for Oncology" to improve the quality of care for individuals using OAMs. Work on this initiative began in 2022 to identify research and measurement opportunities aimed at assessing the quality of OAM use.

PQA is a national quality organization dedicated to improving medication safety, adherence, and appropriate use. A measure developer, researcher, educator, and convener, PQA's quality initiatives support

better medication use and high-quality care. PQA was established in 2006 as a public-private partnership with the Centers for Medicare & Medicaid Services. PQA was created because prescription drug programs were a major area of health care where there was no organization or national program focused on quality improvement. Today, PQA is an independent, non-profit organization with nearly 240 diverse members across health care.

Quality measures are tools that quantify health care processes, outcomes, patient perceptions, and organizational structures or systems to assess the quality of care patients receive with the aim of achieving a more equitable, safe, and affordable health care system that enables all individuals to achieve optimal health and well-being.[1]

This OAM quality initiative is led by the PQA Quality Innovation and Research Center (QuIRC), a strategic initiative to accelerate progress in medication use quality focused on clinical outcomes and provider contributions to care. QuIRC brings together the data, infrastructure and resources needed to develop new, complex quality measures; support their implementation; and create tools and solutions for improving medication use and medication management services. QuIRC is ideal for answering the methodology questions needed to advance the prioritized health plan measure concept for adherence or persistence to OAMs.

Although prior efforts have focused on oncology quality measurement gaps,[6-8] little progress has been made to develop meaningful OAM use quality measures to assess health plan and pharmacy performance. Due to the complex nature of anticancer medication therapy, there remains a dearth of such measures and supporting evidence. Considering the challenges and complexity of creating standardized, OAM-related performance measures for a national quality program, PQA convened a series of multi-stakeholder workshops informed by an environmental scan. This report describes this initial phase of PQA's OAM quality initiative, including a summary of the overall approach, the environmental scan and findings, and key takeaways from the three workshops. The report concludes with PQA's planned next steps.

APPROACH

PQA convened 23 national clinical and methodological experts and patient representatives to participate in three *PQA Convenes* workshops between late 2022 and early 2023 to prioritize OAM quality research and measurement opportunities. In addition to three patients with lived experience, OAM subject matter experts included stakeholders from pharmacies, health plans, health care providers, biopharmaceutical companies, associations, and academia.

These 23 participants invited to serve as advisors were selected to be representative of OAM experts and stakeholders. An additional 16 workshop attendees, including additional subject matter experts and sponsors, participated in an observational role. The workshop series was supported in part through funding from Boehringer Ingelheim, Jazz Pharmaceuticals, Johnson & Johnson, Novartis, EMD Serono, Pfizer, and the Hematology/Oncology Pharmacy Association. Three advisors including one patient also served on a planning committee that met five times to inform workshop content, activities, and direction.

Workshop discussions were informed by an expansive environmental scan conducted by PQA to identify OAM quality issues and existing relevant measures. An environmental scan, which often occurs in the conceptualization phase of a project or measure development, is intended to identify current issues and opportunities influencing strategic direction through a review of the literature, clinical practice guidelines, existing measures, and with input from experts and patients, and other related activities. Quality issues are defined as a gap in quality of care, and quality of care refers to the degree to which health services for individuals and populations increase the likelihood of desired health outcomes. OAMs refer to cytotoxic medications, immunomodulators, targeted therapies, and hormonal medications. While some of these medications may be formulated for more than one route of administration (e.g., parenteral, oral), others such as targeted therapies (e.g., tyrosine kinase inhibitors) and hormonal agents (e.g., tamoxifen) tend to be available primarily in oral-only formulations.

The evaluation of measure concepts during the workshops was framed by standard measure criteria, which include measure importance, scientific acceptability, feasibility, and usability. These criteria are critical for identifying and vetting measure concepts that can be successfully developed and effectively used in real-world settings.

Standard Measure Evaluation Criteria

Importance – measure is focused on a priority area, is evidence based, and can have a positive impact on health care quality

Scientific Acceptability – the measure will produce consistent (reliable) and credible (valid) results about the quality of care

Feasibility – data needed to calculate the measure are readily available for measurement and retrievable without undue burden

Usability and Use – opportunity for implementation and the performance results can be used for both accountability and performance improvement

Workshop 1 (online)

- Review measure fundamentals
- Prioritize quality issues
- Assess existing measures

Workshop 2 (in person)

- Discuss measure criteria
- Prioritize quality issues based on criteria
- Create case for measures

Workshop 3 (online)

- Discuss research priorities
- Build consensus
- Take action

The first and third one-half day workshops were held online via Zoom on December 8, 2022, and April 13, 2023. The second full-day workshop was held in-person on March 2, 2023, in Alexandria, Va. Workshop 1 focused on reviewing the environmental scan findings and prioritized quality issues based on the criterion of importance. Workshop 2 focused on prioritizing health plan and pharmacy measure concepts for potential development by applying the three remaining measure criteria: feasibility, usability, and scientific acceptability. The goal of Workshop 3 was to determine the next steps for PQA to improve the quality of OAM use through quality measurement and research and focused on the top two measure concepts prioritized by the advisors in the second workshop.

ENVIRONMENTAL SCAN

The OAM environmental scan included a review of the literature, existing measures, and clinical practice guidelines to identify:

1. Quality issues discussed in published literature (e.g., peer-reviewed scientific sources or grey literature from reputable sources), and
2. Existing measures potentially relevant to OAM treatment.

QUALITY ISSUES IN OAM TREATMENT

Brief Methods

A review of the scientific peer-reviewed literature was conducted with the objective to identify quality issues associated with OAM use. The review used specific search terms to ensure sufficient sensitivity to capture studies that examined topics with potential quality issues related to OAM use in the United States, and covered literature published from 2012 to 2022. Articles examining potential quality issues were included if they were related to adults receiving OAM treatment.

The review was scoped to identify quality issues associated with OAM treatment that have the highest potential for measure development in the near term and implementation into national accountability programs for medication use in adult populations. The pediatric population, individuals receiving hospice care, and patients receiving inpatient cancer treatment were considered out of scope. In addition, articles that evaluated the comparative effectiveness of OAMs, cost implications of OAM use and consequent financial distress, and those that examined patient-reported outcomes and quality of life were also excluded. These parameters were also selected with measurement attribution in mind. Measure attribution is the selection of the appropriate entity to be assigned the responsibility for performance on a quality measure. One of the key principles to consider during identification of the appropriate accountable entity is actionability or the ability to influence performance on a measure through changes in processes of care.[5, 9] Inappropriate attribution holds entities accountable for a process in which they may have little to no effect on the outcome. For these reasons, the literature review did not include topics like financial toxicity, access, or quality of life and instead focused specifically on treatment. Treatment was defined as recommendation, receipt, initiation, or adherence to OAMs.

This literature review identified quality issues associated with OAM use in the United States. As advancements in oral oncology therapy continue to evolve to enhance survivability and quality of life for patients with cancer, there is increasing urgency to concurrently and more robustly address quality of care associated with OAM use. The eight quality issues identified in the review and presented below provided guidance and context for the workshop discussions to prioritize opportunities to improve the quality of OAM treatment. The findings should be considered representative, but not exhaustive, of quality issues related to OAM treatment as defined by parameters outlined in this report.

Key Findings

Quality Issues

Eight quality issues related to OAM use were identified from the literature (listed alphabetically).

1. Adherence or persistence
2. Disparities
3. Dosing errors
4. Drug interactions
5. Drug waste management
6. Patient education
7. Time-to-treatment
8. Toxicity monitoring and management

Adherence or persistence. Adherence and persistence were identified as quality issues related to OAM in 35 studies. Numerous methods were identified for measuring OAM adherence and persistence in both objective (i.e., independent of patient report or recollection) and subjective ways (survey-based approaches, patient interviews, medication calendars). Proportion of days covered (PDC) and medication possession ratio (MPR) were the most frequently used objective measures of adherence employed in the literature. Twelve studies assessed adherence with PDC methodology, the proportion of days in which a person has access to a medication over a given period of interest.[10-21] Twelve studies assessed adherence using the method of MPR, which captures the total days' supply of a medication dispensed to an individual over a given period.[17, 22-32] Five studies captured adherence using sources of data other than administrative claims, e.g., medication event monitoring systems (MEMS) and pill counts.[33-37] There was variation in the reported methods used to calculate PDC and MPR across these studies, including differing definitions of measurement periods. Most of the studies included patients with breast cancer being assessed for adherence to at least one form of adjuvant endocrine therapy (i.e., tamoxifen or an aromatase inhibitor).

Non-persistence to or discontinuation of OAMs was evaluated in 10 studies.[10, 21, 22, 24, 32, 38-42] Non-persistence or discontinuation was defined as lapses in therapy between 45 and 180 days, with 90 days most commonly used as a cut-point. Nine of the 10 studies assessed non-persistence to or discontinuation of tamoxifen or aromatase inhibitors for breast cancer.

Overall, the environmental scan identified methodological inconsistencies in the approaches to measuring adherence and persistence. This finding was not surprising given the nature of OAMs and their varying recommended durations of use. Even beyond OAMs, operational definitions of terms like adherence and persistence can vary substantially in practice. However, these findings further underscore the need for standardized measurement to enable accurate assessment of performance and comparison across measured entities.

Disparities. Disparities were identified in the areas of OAM treatment, receipt, and adherence. For example, older patients, patients in minority racial categories (e.g., African Americans or American Indians/Alaska Natives), patients with a lower income, patients living in areas with a higher Area Deprivation Index (ADI), and patients with less social support (e.g., measured using marital status) were less likely to receive or initiate adjuvant endocrine therapy for breast cancer.[11, 43-45] Insurance status and treatment location (e.g., academic center vs. community health center) affect the likelihood of OAM treatment initiation or prescription abandonment.[45, 46] Overall, factors associated with disparities in adherence to OAM included age, income, race/ethnicity, level of education, geographic location, social network/support, and insurance status.[11, 16, 43, 44, 47-51]

Dosing errors, toxicity, and drug interactions. OAMs generally have a narrow therapeutic index, with a narrow window between their effective doses and those with potentially adverse toxic effects and require monitoring for both effectiveness and toxicity. Dosing errors are reportedly the most common form of medication errors related to cancer treatment, where under-dosing increases the likelihood of inadequate treatment response and over-dosing increases the likelihood of medication toxicity.[52, 53] In an investigation of medication errors from the literature and incident reports, the most common anticancer medication errors included wrong dose (38.8%), wrong drug (13.6%), wrong number of days supplied (11%), and missed dose (10%).[53]

Comprehensive medication review programs and pharmacist-driven medication therapy management services could serve as key cancer treatment checkpoints to detect dosing errors, toxicity, or drug interactions.

OAMs also can interact with other medications or substances that the patient is concomitantly taking (e.g., drug-drug interactions, drug-food interactions, or drug-herb interactions).[52, 54-56] While vigilant monitoring programs may help with timely detection of errors and treatment complications, there is variation in the completeness of information within drug interaction databases.[57, 58] The sensitivity and specificity of the different types of drug interaction databases on the market (e.g., Lexi-Interact, MicroMedex, Facts & Comparisons, Drugs.com) introduce concern about the level and depth of information that clinicians can offer their patients at the time of counseling.[57, 58] Given the rapidly changing environment around OAMs and the increased use of accelerated FDA approvals, keeping up to date with drug interactions may continue to be a challenge and a potential quality issue.

A few studies and pharmacy-specific guidance documents state that routine comprehensive medication review programs and pharmacist-driven medication therapy management services could serve as key cancer treatment checkpoints to detect dosing errors, toxicity, or drug interactions,[52, 54-56] all of which were identified as quality issues associated with OAM use.

Drug waste management. Health care providers who are prescribing, dispensing, and managing OAMs for patients with cancer must regularly counsel patients about safe handling of OAMs at home as a hazardous substance and provide means and referrals for the return of unwanted or unused OAMs. Not only is there an environmental safety concern, but OAM wastage is costly. Proactive management of potential OAM waste has resulted in cost savings to the health system and the patient.[59, 60] Paying attention to drug waste management reflects an opportunity for the health system to recoup and properly handle these medications while evaluating their safety and usefulness to reallocate to other patients in need.

Patient education. Two studies identified suggest that the education provided to patients is a potential quality issue and an opportunity for improvement. In one study of 175 patients with non-small cell lung cancer (NSCLC), of whom 32% were prescribed OAM for first-line treatment, it was found that documentation of discussions regarding the goals and course of chemotherapy administration for patients with metastatic NSCLC did not meet the American Society of Clinical Oncology (ASCO) Quality Oncology Practice Initiative (QOPI) quality standards for education prior to commencing treatment, especially for individuals prescribed oral agents.[61] In another single center study examining the effect of a newly initiated pharmacist-driven education and consent process for patients receiving OAMs in a predominantly minority, rural and economically disadvantaged population, baseline education and consent rates were reported at 17.9% but rose to 87.0% within the first 15 months of instituting the intervention, suggesting that pharmacists can effect change related to patient education for OAM treatment.[62]

Time-to-treatment. Once patients are offered and have consented to treatment, the timeliness of receiving the medication is another quality issue identified in the literature. Several studies reported time-to-treatment,[46, 63-65] which is defined as the number of days between the prescribing date and the first fill date and can be used as a proxy for treatment initiation. The studies did not use an evidence-based threshold for time-to-treatment, but a lower mean or median time-to-treatment was desired. One study used claims data from 2014 and 2015 and found that OAM time-to-treatment averaged 34.8 days.[46] A more recent, single-center study found that time to OAM treatment at an internal health system specialty pharmacy was on average 5 days compared to an external health system specialty pharmacy which averaged 27 days.[63] This variation in time-to-treatment potentially represents an area for improvement.

EXISTING QUALITY MEASURES POTENTIALLY RELEVANT TO OAM TREATMENT

Brief Methods

Identifying measures relevant to OAM treatment is important to avoid development of a duplicate measure and to determine if any existing measures have the same focus, target population, or measure elements for the purpose of measure harmonization. Measure harmonization is the standardization of measure specifications when they overlap in focus, population, or other measure elements.[66] To identify existing measures relevant to OAM treatment, publicly available sources were scanned, including the National Quality Forum Quality Positioning System,[67] the Centers for Medicare & Medicaid Services (CMS) Measures Inventory Tool,[68] the Qualified Clinical Data Registry measures,[69] the CMS National Impact Assessment,[70] NCQA HEDIS measures,[71] the Core Quality Measures Collaborative,[72] and other oncology-specific measurement programs.[73-75] Additionally, the full list of CMS quality programs was reviewed to identify potentially relevant OAM measures. This search may not encompass all OAM-relevant measures because some measures may not be available in the public domain. When measure specifications are not publicly available, it is not possible to determine the exact agents included in measures whose titles broadly describe a focus on chemotherapy.

Key Findings

A total of 121 potentially relevant oncology-related measures were identified. A review of publicly available measure information describing the measures resulted in 79 of the 121 measures being excluded since they were unrelated to medication use and another 11 measures excluded because they were not focused on OAMs. The result was 31 measures (25.6%) deemed potentially relevant to OAM treatment **(Appendix A)**. The identified measures were primarily clinician-level measures that covered domains such as the receipt of therapy, monitoring of therapy, side effect management, and patient-provider communication. These existing measures at least partially address the identified quality issues of patient education, time-to-treatment, and toxicity monitoring. Many of the existing measures were narrowly focused on a specific cancer type or stage of diagnosis or were broader but focused on documentation. Measures that do not evaluate the quality of an activity and that can be met primarily through documentation are not preferred.[76] Therefore, measurement gaps were found for quality issues related to OAM adherence and persistence, dosing errors, drug interactions, and drug waste management. Overall, the environmental scan revealed a lack of relevant OAM-related quality measures for health plan and pharmacy performance assessment. This therapeutic area has grown substantially over the past decade and projects to continue growing, but quality measures directly focused on OAMs are severely limited. Existing measures include a pair of measures for recommendation and receipt of tamoxifen in individuals with breast cancer, one measure combining that pair of concepts, and a fourth measure also focused on adjuvant hormonal therapy for breast cancer, likely with overlapping medications.

Many measures included in **Appendix A** are medication-related but may be described as medication-adjacent. These are process measures that relate to activities proximal to medication prescribing, such as documentation, patient discussion of goals or risks, screening and assessment. These types of measures have critical roles to play in the healthcare system and address important, patient-centric aspects of oncology treatment. However, their frequency combined with the dearth of directly relevant measures demonstrates a need for OAM measures.

Overall, the environmental scan revealed a lack of relevant OAM-related quality measures for health plan and pharmacy performance assessment. This therapeutic area has grown substantially over the past decade and projects to continue growing, but quality measures directly focused on OAMs are severely limited.

PQA CONVENES WORKSHOP SERIES

WORKSHOP 1

The workshop series kicked off with an overview of PQA's OAM quality initiative, including the objectives, scope, and approach. The standard criteria used to evaluate quality measures were reviewed, including the *importance* of a measure concept, *feasibility* to measure, the *scientific acceptability* of the measure's construct, and the measure's *usability*.

The main goal of Workshop 1 was to focus on the importance criterion by determining what the quality issues are and assessing which quality issues are measurement priorities. The importance criterion focuses on the extent to which a measure concept addresses a specific priority, affects large numbers of patients, addresses high resource use, or has severe consequences that may occur related to poor quality.

The evidence supporting the eight quality issues related to OAM use identified from the literature were presented for the 23 advisors to share their perspective during breakout sessions related to the criterion of importance.

1. Adherence or persistence
2. Disparities
3. Dosing errors
4. Drug interactions
5. Drug waste management
6. Patient education
7. Time-to-treatment
8. Toxicity monitoring and management

Advisors suggested the following four quality issues in addition to those identified in the literature:

- Access to OAMs, which includes medication affordability and financial toxicity
- Patient education, coaching or support
- Primary medication non-adherence (PMN) or prescription abandonment
- Variability in how OAMs are or can be used

Advisors acknowledged the interrelated nature of the quality issues, making it difficult to assess each as separate issues. For example, the quality of medication toxicity management and monitoring affects medication adherence or persistence. In addition, advisors noted the intersection of disparities with each of the quality issues. Furthermore, workshop advisors agreed that patient education is important prior to initiating therapy but expanded the concept of education as critical throughout treatment and a key quality improvement endeavor, which affects other quality issues, e.g., toxicity, adherence.

Advisors also highlighted that unlike medication use for other chronic conditions, where PDC is a suitable method to evaluate adherence, pre-planned breaks in cancer treatment (often referred to as 'drug holidays') are not uncommon, so accounting for clinically appropriate non-adherence and evaluating non-conventional methods of measurement would be critical when assessing OAM adherence or persistence.

During the breakout sessions, each group selected the top four quality issues and ranked them using the following framework to assess the importance criterion for subsequent full-group discussion:

- I agree that this is a quality issue in OAM use.
- My stakeholders would agree that this is a quality issue in OAM use.
- There is likely evidence to support the process-outcome linkage and effective interventions to improve care.

PQA presented the results of the environmental scan for related, existing quality measures to the full group, followed by breakout groups for discussion. The 31 identified quality measures **(Appendix A)** were framed related to their association with the quality issues highlighted earlier. During breakout discussions, advisors discussed measure attributes such as measure type and levels of analyses to assess the potential for adapting existing measures to other levels of analysis, such as pharmacy or health plan. Many of the existing quality measures were process measures specified for clinician-level performance assessment, and advisors agreed that future work should focus on health plan and pharmacy

measure opportunities, due to the lack of standardized OAM use quality measures to assess these entities' performance.

Overall, advisors considered the most important existing measures to be broad in focus such as antiemetic protocols, documentation of treatment intent and planning, assessing or addressing medication adherence at each clinically significant interval, and specialty pharmacy turnaround time. However, the existing measures were noted to have varying importance as they relate to OAM use specifically since some measures, such as the measure assessing antiemetic protocols, would depend on the type of OAM used and whether nausea/vomiting are a recognized and consistent issue for that specific medication.

Many of the existing quality measures were process measures specified for clinician-level performance assessment, and advisors agreed that future work should focus on health plan and pharmacy measure opportunities, due to the lack of standardized OAM use quality measures to assess these entities' performance.

At the conclusion of the workshop, advisors were asked to collectively rank the quality issues based on their reflections and the discussions shared throughout the day. Their votes produced the following prioritized list of OAM use quality issues considering importance as the criterion:

1. Adherence or persistence
2. Primary medication nonadherence or prescription abandonment rate
3. Time-to-treatment
4. Patient education
5. Toxicity monitoring and management
6. Drug waste management

WORKSHOP 2

The goal of Workshop 2 was to prioritize health plan and pharmacy measure concepts for potential development by applying the three remaining measure criteria: feasibility, usability, and scientific acceptability. Discussions were specific to health plan and pharmacy measurement, based on (1) environmental scan findings indicating a significant gap in OAM use quality measures for these levels of accountability; and (2) alignment with PQA staff expertise and experience, thereby presenting the greatest actionability and likelihood for PQA to pursue follow-on work prioritized by this PQA Convenes.

The feasibility criterion focuses on data to gauge data availability, accessibility, and quality. Multiple factors, such as fragmentation of data, data interoperability, patient privacy, and the limited governance around data sharing, can impact the accessibility of data.[5, 9] Often in quality measurement, the most accessible and least burdensome data sources are administrative data and claims data. However, these sources have limited degrees of clinical information available as the primary purpose of these sources is to provide information for administrative items (i.e., admissions, discharges) and billing of services provided. Another feasibility consideration is the timeliness, completeness, and accuracy of data. Additional data sources, such as clinical records, patient reported information, and registries often contain important and rich clinical information. However, the availability, accessibility, burden, and cost of using these as data sources for national performance measures can be prohibitive and must be considered during the assessment of feasibility.

The usability criterion refers to the opportunity for implementation of a quality measure into an accountability or quality improvement program. Both accountability and quality improvement programs utilize quality measurement to assess the performance and improvement of a population or of health plans, providers and other clinicians in the delivery of health care services.[77] Measuring quality in an accountability program (e.g., Medicare Part D Star Ratings) requires standardized data collection and reporting of results across measured entities, whereas quality improvement programs are internal to organizations, have a great deal of flexibility, and can adapt to the needs and resources of the organization.

The scientific acceptability criterion refers to a measure's reliability and validity and depends on having a sample size that is balanced and large enough to produce meaningful results. Reliability refers to the measure being implemented consistently and whether it can accurately differentiate performance among measured entities. Validity refers to the degree to which evidence, clinical judgement, and theory support interpretations of a measure's performance. In other words, validity is the extent to which the measurement results accurately measure what is intended to be measured. A reliable and valid measure provides consistent and credible information about the quality of care.

The workshop advisors were split into two breakout groups. Each group, moderated by a PQA staff member, discussed the three measure criteria in the context of each measure concept, including considerations specific to health plan measurement and pharmacy measurement. Each group then provided a consensus-determined perceived feasibility and usability rating for each measure concept. See **Figure 1** below for a depiction of the breakout group and measure concept rating process.

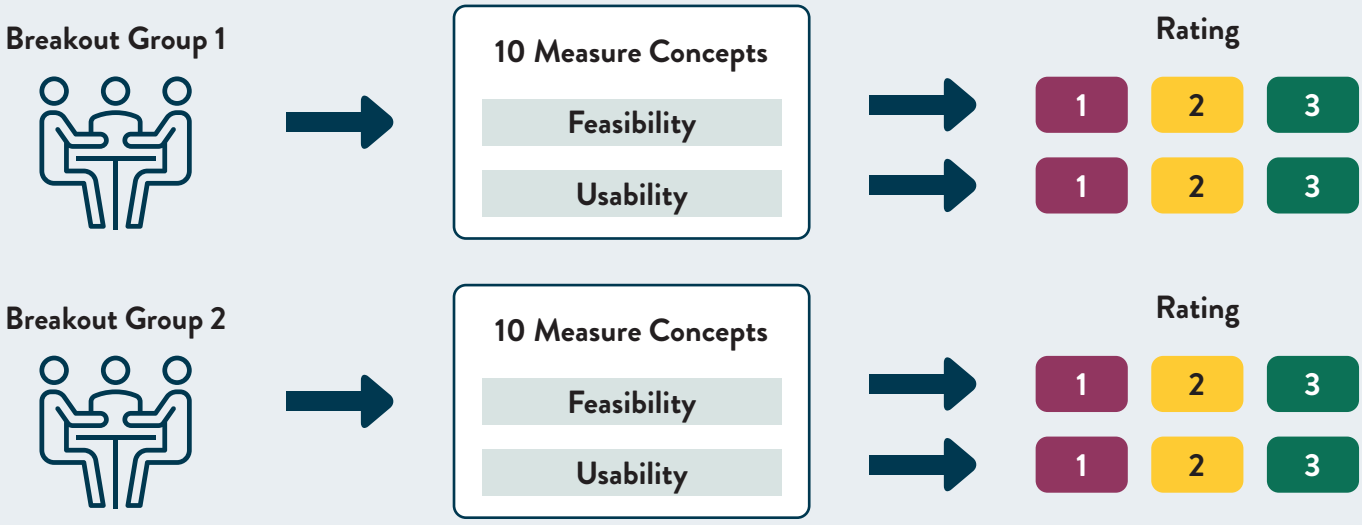
Feasibility ratings used a 1 – 3 scale:	
1	Pharmacies/payers would require more than one year to document and report the data needed to calculate the measure concept, with significant additional resources or changes to infrastructure
2	Pharmacies/payers would be able to document and report the data needed to calculate the measure concept within the next year, with limited additional resources or changes to infrastructure
3	Pharmacies/payers can document and report the data needed to calculate the measure concept today, with current resources and infrastructure

Usability ratings used a 1 – 3 scale:	
1	Pharmacies/payers are not likely to adopt the measure concept
2	Pharmacies/payers are somewhat likely to adopt measure concept
3	Pharmacies/payers are highly likely to adopt the measure concept

Since the scientific acceptability (reliability and validity) criterion is determined through measure testing, the workshop advisors discussed this criterion to a lesser extent and did not provide a rating.

An overview of the discussions that took place throughout the workshop related to assessments of feasibility, usability, and scientific acceptability for each of the measure concepts is summarized below. It should be noted that disparities in OAM treatment is a cross-cutting quality issue that would be assessed during the development of quality measures rather than the specific focus of a measure. This allows disparities to be analyzed through stratification of measures focused

FIGURE 1



on care processes and outcomes. Further, patient education is a quality improvement intervention that can be leveraged to address many quality issues like those identified here. Therefore, disparities in OAM treatment and patient education were not further discussed and are not included in the summaries below.

Adherence or Persistence

Measuring adherence or persistence to OAMs was recognized as a high priority; however, workshop advisors in both groups felt that more research would need to be conducted to develop an appropriate method of determining adherence or persistence to OAMs. This is because the PDC method, which is commonly used to determine adherence, assumes that individuals are taking their medications as prescribed on a continuous basis without breaks in therapy. Given the nuances in how OAMs are used, the PDC method may not provide an accurate assessment of adherence for certain OAMs, especially those with higher toxicity profiles. A method that can differentiate unintended nonadherence from intentional withholding of therapy, or clinically appropriate breaks in therapy (e.g., 'drug holidays,' temporary dose reduction or withholding of therapy) is vital. Workshop advisors also suggested that measuring time on therapy may be suitable when evaluating OAM use because it would allow for changes in clinically driven adjustments to the treatment regimen rather than adherence based on consistent fills alone. However, operational definitions of time on therapy were not further discussed. Workshop advisors agreed that evidence exists linking better adherence and persistence to OAMs with improved patient outcomes and believed that this would be a priority area for measurement in Medicare quality programs, including the upcoming Enhanced Oncology Model.

Given the nuances in how OAMs are used … a method that can differentiate unintended nonadherence from intentional withholding of therapy, or clinically appropriate breaks in therapy (e.g., 'drug holidays,' temporary dose reduction or withholding of therapy) is vital.

Workshop advisors noted that to be useful, diagnosis-related data would be essential, which may make the measure more appropriate for Medicare Advantage rather than for Prescription Drug Plans (PDPs) given that standalone PDPs lack timely access to medical claims. Advisors emphasized the need for a validation study to determine an appropriate method to assess adherence or persistence.

Primary Medication Nonadherence or Prescription Abandonment Rate

Primary medication nonadherence (PMN) occurs when a new medication is prescribed for a patient, but the patient does not obtain the medication or an appropriate alternative within a defined time period. A related concept, prescription abandonment, traditionally refers more broadly to situations in which any prescription is filled by a pharmacy but not obtained by the patient; as a result, reports of abandonment rate may not be limited to new prescriptions and may capture refilled prescriptions that are abandoned. Key concerns with measuring PMN or prescription abandonment rate included considerations about patients changing pharmacies where the appearance of abandonment in one pharmacy may not necessarily mean the patient did not receive their prescription altogether; the recognition that there are a wide variety of OAMs, and not all types of OAMs are available from every pharmacy (e.g., limited distribution drugs, for which manufacturers limit the distribution of the drug to only a few pharmacies); and the acknowledgment that more granular data from the pharmacy management system may be needed to appreciate whether abandonment is documented as a patient choice or refusal (and potentially outside of the pharmacy's control). In addition, advisors raised concerns about different types of OAMs and whether

the appropriate treatment is covered under the medical benefit versus drug benefit, which would have implications on the types of data required to capture prescription abandonment or PMN.

Time-to-Treatment

The time-to-treatment measure concept was prioritized for pharmacy measurement. Building on definitions from the literature and discussions from the first workshop, PQA staff provided two draft definitions for this concept to support participant discussions and assessment during the second workshop. Those draft definitions are:

1. The average number of days between the prescribing date and the first fill date.
2. The percentage of individuals whose prescription for a new OAM was filled within a certain number of days of being ordered by the prescriber.

Workshop advisors noted that time-to-treatment is an important concept to measure because ensuring patients receive timely treatment is critical to optimizing outcomes. Advisors debated about which points in time are captured regularly, documented consistently, and can be reported from pharmacy systems, as these are important considerations when assessing the measure concept's feasibility. For the second definition specifically, it was unclear what the appropriate threshold for timeliness should be and whether this threshold differs based on OAM type, cancer type, and treatment intent. Workshop advisors noted aspects of time-to-treatment that pharmacists can influence, including assistance to navigate the prior authorization process and investment of pharmacy time to work on financial assistance that the patient might need to obtain the medication. Advisors suggested the potential for stratifying time-to-treatment by factors such as medication class and the need for prior authorization. However, workshop advisors acknowledged the possibility of having inadequate denominator sizes if stratification is applied. Advisors agreed that time-to-treatment and prescription abandonment rate are conceptually related in that they can be used to assess access to OAMs. When considering accountability for performance measurement, it also was noted that both pharmacies and health plans play a role in ensuring access related to cost. For example, pharmacies have a role in connecting patients with payment assistance resources and health plans have a role in ensuring benefit design does not inhibit access.

Toxicity Monitoring and Management

Given that medication toxicity and adverse drug events are common causes of nonadherence to OAMs, advisors believed that toxicity assessments should occur, and are already happening, though these assessments may not be documented consistently in terms of breadth or depth. As such, advisors felt that when assessing toxicity monitoring and management, a documentation measure aimed at capturing the occurrence of these encounters could be meaningful.

Drug Waste Management

Advisors noted that drug waste was a very important issue because medication cost is a significant contributor to financial toxicity in cancer care. This proposed measure concept is intended to reduce drug waste by preventing unnecessary dispensing of an OAM, and by doing so, reduce avoidable costs to patients and the health care system. Advisors emphasized the need for more research to develop a standardized approach to examine the issue of drug waste since the approach used by certain institutions today may not be scalable due to a lack of availability and standardization of data elements that would be required to calculate such a measure.

Rating Measure Concepts for Feasibility and Usability

Upon discussing the measure concepts as they related to specific levels of analyses (i.e., pharmacy measurement, health plan measurement), advisors in each breakout group provided ratings for feasibility and usability based on their perception of the readiness to measure the proposed concept and their judgment of the likelihood that the measure would be adopted in accountability programs. **Table 1** (on next page) shows the top 5 concepts and corresponding ratings of feasibility and usability. Notably, both groups' ratings of each of these criteria were very closely aligned.

Advisors showed greater concern related to feasibility and usability for toxicity monitoring and management and drug waste management for both pharmacy and health plan measurement. Advisors suggested that adherence or persistence, and PMN or prescription abandonment rate were measure concepts that reflected consistent and promising levels of readiness and likelihood of adoption for both pharmacy and health plan measurement. At the same time, the time-to-treatment concept raised some concerns about feasibility, especially for health plan measurement.

Table 1. Summary of Feasibility and Usability Ratings from Each Breakout Group				
Measure concepts by level of analysis	Feasibility		Usability	
	Group 1	Group 2	Group 1	Group 2
Pharmacy-level				
Adherence or persistence	2	3	3	2
Prescription abandonment rate or PMN	2	3	3	3
Time-to-treatment	3	3	2	2
Toxicity monitoring and management	2	1	2	1
Drug waste management	1	2	2	2
Health Plan-level				
Adherence or persistence	2	3	3	2
Prescription abandonment rate or PMN	2	3	3	3
Time-to-treatment	3	1	3	2
Toxicity monitoring and management	2	1	2	1
Drug waste management	1	3	2	3

a. Feasibility ratings using a 1 – 3 scale:
[1] not likely to adopt the measure concept; [2] somewhat likely to adopt measure concept; [3] highly likely to adopt the measure concept.
b. Usability ratings using a 1 – 3 scale:
[1] pharmacies/payers would require more than one year to document and report the data needed to calculate the measure concept, with significant additional resources or changes to infrastructure; [2] pharmacies/payers would be able to document and report the data needed to calculate the measure concept within the next year, with limited additional resources or changes to infrastructure; [3] pharmacies/payers can document and report the data needed to calculate the measure concept today, with current resources and infrastructure.

Finally, advisors were asked: Out of all 10 measure concepts, select your top three priorities for PQA to consider for development. This reprioritization exercise was done by considering all the measure criteria to the extent possible at this early stage. The voting results are shown in **Table 2**.

Table 2. Voting results showing participant selection of top three measure concepts for development consideration (N = 23)		
Rank	**Measure Concept**	**Level of Analysis**
1.	Adherence or persistence	Health Plan
2.	Time-to-treatment	Pharmacy
3.	Time-to-treatment	Health Plan
4.	PMN or prescription abandonment rate	Health Plan
5.	Adherence or persistence	Pharmacy
6.	Drug waste management	Health Plan
7.	PMN or prescription abandonment rate	Pharmacy
8.	Toxicity monitoring and management	Health Plan
9.	Drug waste management	Pharmacy
10.	Toxicity monitoring and management	Pharmacy

WORKSHOP 3

The goal of the last workshop was to determine the next steps for PQA to take to improve the quality of OAM use through quality measurement and research. The agenda was centered around the top two measure concepts prioritized by the advisors in the second workshop: (1) adherence or persistence for health plan measurement and (2) time-to-treatment for pharmacy measurement.

Adherence or Persistence (Health Plan)

Adherence or persistence was identified as a quality issue through a review of the literature and prioritized by advisors in the second workshop. The concept was described as a method of assessing that individuals have taken their OAMs as prescribed over a given time period, while acknowledging that the appropriate adherence or persistence threshold for OAMs during a specific measurement period needs to be defined. Therefore, during the third workshop, advisors were provided with an overview of approaches that have been used to evaluate adherence, persistence, and completion of medication therapy in quality measurement—inclusive of the PDC methodology, as well as other methods. Advisors were vocal regarding the methodological approach to assessing adherence, stating that it should not be the PDC methodology due to unique aspects of OAM treatment like 'drug holidays.' Advisors noted that it would be most useful to select a few cancers and medication classes with less complex regimens, to test a specific methodology and validate against oncology-specific outcomes. It was noted that different methodologies to assess persistence to OAM use might be required due to the availability of a variety of medication types and the variability in how these medications are used clinically. The discussion was guided by a series of questions, all of which require much further exploration:

Methodology considerations

- Is there evidence to support specific gap or timeframe definitions?
  - Are there timeframes where continuation of OAM therapy as prescribed is most critical to achieve optimal outcomes?
  - Are there points in time where adherence or persistence generally declines?
  - When do we anticipate seeing toxicity impact?
  - Would an approach similar to the PQA insulin persistence methodology be appropriate?[78]

Clinical considerations

- Which drugs/regimens would be most appropriate to measure?
- Which drugs/regimens require strictest adherence or persistence for clinical benefit?
- Which drugs/regimens have the greatest evidence demonstrating benefits of adherence or persistence?
- Consider that measuring common therapies may have greater impact than rare therapies
- Account for cycling medications: prescribed regimen vs. toxicity-based 'drug holiday'
- How can we differentiate poor quality or lack of adherence or persistence from planned, clinician-recommended breaks in treatment?

Feasibility considerations

- What data sources are needed to capture the necessary data elements for this health plan measure concept?
- Potential strategies for identifying OAMs that could be grouped together in a single measure:
  - Duration of therapy
  - Types of cancer
  - Specific classes of OAMs
  - Certain OAMs prone to toxicities

Time-to-Treatment (Pharmacy)

Time-to-treatment was a concept identified as a quality issue through a review of the literature and then highly prioritized for pharmacy measurement by advisors in the second workshop. As noted above, the group considered two potential definitions for this measure concept.

Discussions during the second workshop evolved to focus on the description of the average number of days between the prescribing date and the first fill date.

Given this prioritization, PQA staff felt it was important to ensure the group had sufficient understanding of similar measures available and in development by PQA. Therefore, during the third workshop, advisors were provided with an overview of the PQA-endorsed *Specialty Pharmacy Turnaround Time* measure[79] (endorsed in 2021) that is available for use, and the *Specialty Pharmacy Prescription Abandonment Rate* measure concept[80] that PQA has in development. See **Figure 2** for a depiction of the medication access continuum and these related pharmacy measures or measure concepts.

Both measures include oncology treatments, in addition to several other specialty conditions and medication categories. The discussion centered around the potential to use stratification for measures available and in the near term to focus on OAMs, or whether there would be sufficient added value in allocating resources to develop an OAM-specific measure assessing time-to-treatment. See Figure 2 for a depiction of the overlap across the related measures or measure concepts.

After considerable discussion, a formal poll was conducted to determine the advisors' recommendations on next steps for this measure concept. The polling question was as follows:

> Given that the endorsed *Specialty Pharmacy Turnaround Time* measure and the Specialty Pharmacy Prescription Abandonment Rate measure in-development cover 3 of the 4 steps that time-to-treatment encompasses, does the incremental value of time-to-treatment warrant the considerable resources needed to develop a third related measure?

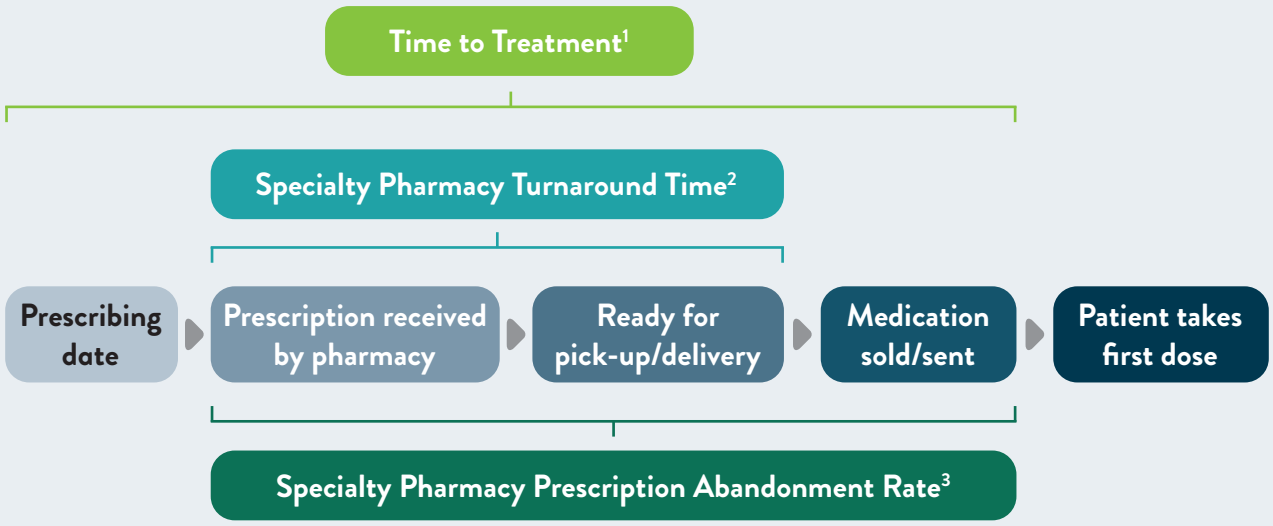
Twelve of 21 (57.1%) workshop advisors who voted said that the development of a time-to-treatment measure is warranted to advance the quality of OAM use attributable to the pharmacy. Five advisors (23.8%) said this was unwarranted and four (19.0%) were unsure.

Research Topics

In addition to research needed to inform measure development, the following OAM use quality research opportunities were identified through the environmental scan literature review or recommended by workshop advisors:

- Patient education, coaching or support
- Access to OAM, which includes medication affordability and financial toxicity
- Primary medication non-adherence (PMN) or prescription abandonment
- Variability in how OAMs are or can be used
- Patient reported outcomes
- Quality for rare cancer types

FIGURE 2. Depiction of the medication access continuum and three related pharmacy measures or measure concepts.



1. New quality concept | 2. PQA-endorsed pharmacy measure available for use | 3. PQA pharmacy measure concept in development

CONCLUSION AND NEXT STEPS

This initial phase of PQA's initiative to improve OAM use quality brought together experts and stakeholders to prioritize measurement and research opportunities informed by a robust environmental scan. Twenty three advisors, including patients, met for three workshops over the course of several months, resulting in prioritized OAM quality issues, prioritized lists of health plan and pharmacy measure concepts, and proposed next steps.

Oncology Quality Innovation and Research Initiatives

Development of quality measures is a resource intensive and lengthy process. The value of a potential measure and its ability to meet the standard measure criteria of importance, scientific acceptability, feasibility, and usability must be evaluated early in the development process. PQA began pre-development efforts through this initiative by incorporating the standard measure criteria into prioritization exercises with multi-stakeholder experts and patients to illuminate existing measurement gaps, understand current and future measurement priorities, and affirm next steps for improving quality for OAM treatment.

The concept of **time-to-treatment** was the top priority for **pharmacy measurement**. As shared with the advisors, and as described in this report, this measure concept has a great deal of overlap with both the PQA-endorsed *Specialty Pharmacy Turnaround Time* pharmacy measure and a PQA pharmacy measure in development, *Specialty Pharmacy Prescription Abandonment Rate*. Furthermore, the aspect of time-to-treatment not already captured in those two measures (i.e., the time from the OAM being prescribed to the time it gets to the pharmacy) is largely outside of the pharmacy's control.

As a result, PQA encourages stakeholders to use the existing *Specialty Pharmacy Turnaround Time* measure and participate in piloting the *Specialty Pharmacy Prescription Abandonment Rate* measure concept. Through these approaches, PQA can continue to assess the degree to which existing and in-development pharmacy measures meet the needs to assess timely access to OAMs, whether refinements to the measures would be beneficial, or if allocating limited resources to additional measure development efforts is warranted.

The aspect of time-to-treatment not already captured in those two measures (i.e., the time from the OAM being prescribed to the time it gets to the pharmacy) is largely outside of the pharmacy's control.

The concept of **adherence or persistence** was the top priority for **health plan measurement** among advisors. Therefore, PQA will focus the next phase of its Quality Innovation and Research Initiative for Oncology on this area. PQA's work will include:

1. Compiling available measure specifications for metrics currently used by organizations for internal assessments of adherence or persistence to OAMs.
2. Identifying methodologies to assess OAM adherence and persistence that may be appropriate for health plan performance measurement.
3. Conducting initial feasibility and validity assessments of prioritized adherence or persistence methodologies.

These steps are described in the following paragraphs.

Compiling Internal Improvement Metrics

A number of organizations have stated that they internally track OAM adherence. PQA will reach out to contacts at these organizations to gather additional information on these internal metrics, including measure specifications and methods used. Further work is needed to assess whether and which elements of such metrics could be leveraged to inform standardized performance measures suitable for accountability purposes.

Identifying Adherence and Persistence Methodologies for Use in Performance Measurement

The uniqueness of OAMs and their use presents distinct challenges in defining and measuring adherence and persistence to therapy. Examples of complexities of OAM use that pose challenges to standardized measurement include:

- Multiple types of OAMs are available, each with differing purposes in cancer treatment (e.g., neoadjuvant or adjuvant chemotherapy vs. adjuvant endocrine therapy for the prevention of recurrence).
- OAMs are often prescribed as part of complex cancer-specific treatment regimens with less uniform dosing schedules, which in some cases include 'drug holidays' where the provider temporarily discontinues therapy, resulting in clinically appropriate periods of non-adherence.
- It is not uncommon for health care providers to switch OAMs during therapy due to poor response, evidence of drug interactions, or intolerance of side effects.

PQA plans to embark on research projects to explore various methodological approaches designed to inform subsequent measure development opportunities. For example, PQA will identify which OAMs would be most appropriate to group within the same adherence or persistence measure based on factors such as toxicity and cycling profiles. These pre-development efforts are necessary for several reasons. One is that some OAMs also have non-oral routes of administration. For example, busulfan, cyclophosphamide, and others can be administered either orally or by intravenous infusion. Typically, oral preparations are billed under an individual's prescription benefit, and infused products are billed under the individual's medical benefit. This adds an additional level of complexity when individuals change from oral to infused products, as assessing adherence would require aggregation of those data that are frequently captured and stored separately, especially at the national level.

In addition, chemotherapy regimens can be highly complex. Depending on the cancer type, histologic characteristics, stage, biomarkers, and responsiveness, patients may have to contend with varying protocols defined by changes in medication dose, frequency and even duration of treatment for each chemotherapy cycle. In addition, depending on the specific indication and timing (e.g., neoadjuvant, adjuvant or salvage), the dose, frequency, and duration of treatment within a chemotherapy cycle and between cycles can vary considerably.[81] Therefore, identifying a methodology to assess adherence or persistence to OAMs must take into account these factors.

The uniqueness of OAMs and their use presents distinct challenges in defining and measuring adherence.

Conducting Initial Feasibility and Validity Assessments

Available data to determine the quality of OAM use presents significant challenges. Administrative claims data are the most readily available and least burdensome data source.[82] However, claims data lack important clinical information needed to understand the care of patients with cancer, such as stage of cancer and tumor characteristics. The National Quality Forum noted in 2018 that due to limitations of information contained within claims data, it is difficult to discern good from poor quality.[5] For example, if the disease advances or tumor characteristics change, the prescribed treatment may be discontinued. However, without more detailed information in claims, this is indistinguishable from clinically inappropriate patient nonadherence.

Additionally, the methodological approach to adherence or persistence should not be restricted to PDC due to the unique aspects of OAM treatment noted above. Once potential methodologies are identified, PQA will need to assess the feasibility of obtaining and using all data needed for the calculation, and to assess the validity of the calculation in providing an accurate assessment of the degree to which an individual has adhered to their OAM therapy as prescribed and intended.

This report is intended to identify and prioritize opportunities to improve the quality of OAM use. PQA builds consensus, advances thought leadership, and leads numerous measure development, research and education projects to advance medication use quality. Advancing quality at the national level requires numerous commitments and efforts from all stakeholders with roles in the medication use process. PQA encourages the industry to leverage these findings to improve OAM use, including in partnership with PQA where appropriate.

ABOUT PQA

PQA, the Pharmacy Quality Alliance, is a national quality organization dedicated to improving medication safety, adherence and appropriate use. A measure developer, researcher, educator and convener, PQA's quality initiatives support better medication use and high-quality care. PQA was established in 2006 as a public-private partnership with the Centers for Medicare & Medicaid Services. PQA was created because prescription drug programs were a major area of health care where there was no organization or national program focused on quality improvement. Today, PQA is an independent, non-profit organization with nearly 240 diverse members across health care.

The ***PQA Quality Innovation and Research Center*** **(QuIRC)** is a strategic initiative to accelerate progress in medication use quality and focus on clinical outcomes and provider contributions to care. Developing accurate and responsive outcomes-focused measures requires innovative approaches to measure development and research to ensure that measures are valid and useable in real-world settings. Through pilot, demonstration and research projects and consensus-building events, QuIRC answers the difficult questions needed to develop new, complex measures and effectively implement them.

PQA Convenes brings together national leaders in medication use quality to build consensus and develop plans of action to promote innovative and timely opportunities for improving patient care and outcomes. A gathering of diverse thought leaders and decision makers, PQA Convenes is designed to:

- Explore how medication use quality and pharmacist-provided care can improve care delivery, patient and provider experiences, and patient outcomes.
- Clarify unmet market needs, gaps in care, or interventions that can be realized through research, education, and collaboration.
- Provide a collective call to action, which can include (a) white papers or consensus statements; (b) follow-up or expanded convenings; and (c) communications and engagement strategies to build broader awareness.

Visit pqaalliance.org to learn more.

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PQA thanks the 23 workshop advisors, whose collaborative work with our project team over six months, informed this report's recommendations to improve the quality of oral anticancer medication use. Their consensus-based prioritization of medication use quality measure concepts will guide the next phase of the PQA Quality Innovation and Research Initiative for Oncology.

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APPENDIX A: IDENTIFIED QUALITY MEASURES POTENTIALLY RELEVANT TO OAMS

Measure	Type	Steward
Adjuvant chemotherapy is recommended, or administered within 4 months (120 days) of diagnosis for patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer	Process	American College of Surgeons
Adjuvant chemotherapy received within 4 months of diagnosis by patients with AJCC stage III colon cancer	Process	American College of Surgeons
Adjuvant chemotherapy recommended for patients with AJCC stage IA NSCLC (Lower-Score Better)	Process	American Society of Clinical Oncology
Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer	Process	American College of Surgeons
Antiemetic Therapy for Low- and Minimal-Emetic-Risk Antineoplastic Agents - Avoidance of Overuse	Process	American Society of Clinical Oncology
Appropriate Antiemetic Therapy for High- and Moderate Emetic Risk Antineoplastic Agents	Process	American Society of Clinical Oncology
Appropriate Treatment for Patients with Stage I (T1c)-III HER2 Positive Breast Cancer	Process	American Society of Clinical Oncology
Chemotherapy intent (curative vs. noncurative) documented before or within two weeks after administration	Process	American Society of Clinical Oncology
Chemotherapy intent discussion with patient documented	Process	American Society of Clinical Oncology
Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer	Process	American College of Surgeons
Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients	Process	Formerly PCPI
Combination chemotherapy received within 4 months of diagnosis by women under 70 with AJCC stage IA (T1c) and IB - IIIER/PR negative breast cancer	Process	American College of Surgeons
Combination chemotherapy recommended within 4 months of diagnosis for women under 70 with AJCC stage IA (T1c) and IBIII ER/PR negative breast cancer	Process	American College of Surgeons
Documented plan for oral chemotherapy, including doses, route, and time intervals	Process	American Society of Clinical Oncology

Documented plan for oral chemotherapy: Administration schedule (start day, days of treatment/rest and planned duration)	Process	American Society of Clinical Oncology
Documented plan for oral chemotherapy: Dose	Process	American Society of Clinical Oncology
Documented plan for oral chemotherapy: Indications	Process	American Society of Clinical Oncology
Documented plan for oral chemotherapy: provided to patient/caregiver prior to start of therapy and practitioner(s) providing continuing care (PCP) within 3 months of starting therapy	Process	American Society of Clinical Oncology
Height, Weight, and BSA documented prior to chemotherapy	Process	American Society of Clinical Oncology
Infertility risks discussed prior to chemotherapy with patients of reproductive age	Process	American Society of Clinical Oncology
Number of chemotherapy cycles documented	Process	American Society of Clinical Oncology
Oral chemotherapy monitored on visit/contact following start of therapy: Medication adherence addressed	Process	American Society of Clinical Oncology
Oral chemotherapy monitored on visit/contact following start of therapy: Medication adherence assessed	Process	American Society of Clinical Oncology
Patients with Stage IV NSCLC with adenocarcinoma histology with an activating EGFR mutation or ALK gene rearrangement who received first-line EGFR tyrosine kinase inhibitor or other targeted therapy	Process	American Society of Clinical Oncology
Patients with Stage IV NSCLC with EGFR mutation status unknown or without an activating EGFR mutation or ALK gene rearrangement who received first-line EGFR tyrosine kinase inhibitor or ALK inhibitor	Process	American Society of Clinical Oncology
Signed patient consent for chemotherapy	Process	American Society of Clinical Oncology
Specialty Pharmacy Turnaround Time	Process	Pharmacy Quality Alliance
Systemic chemotherapy is administered within 4 months to day preoperatively or day of surgery to 6 months postoperatively, or it is recommended for surgically resected cases with pathologic, lymph node-positive (pN1) and (pN2) NSCLC	Process	Formerly PCPI
Tamoxifen or AI received within 1 year of diagnosis by patients with AJCC stage IA(T1c) and IB - III ER or PR positive breast cancer	Process	Formerly PCPI
Tamoxifen or AI recommended within 1 year of diagnosis for patients with AJCC stage IA (T1c) and IB - III ER or PR positive breast cancer	Process	Formerly PCPI
Tamoxifen or third generation aromatase inhibitor is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0, or stage IB - III hormone receptor positive breast cancer	Process	Formerly PCPI

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