Impact of Utilization Management Policies for Cancer Drug Therapies

Introduction

Rising healthcare costs, including escalating drug prices, have led to a renewed focus among policymakers, providers, and payers on strategies to guide the effective use of healthcare resources. One such strategy is the development and implementation of utilization management policies, which are payer-imposed administrative rules that may restrict or deny coverage for selected treatments. The American Society of Clinical Oncology (ASCO) is committed to supporting policies that reduce cost while preserving or increasing quality of cancer care. However, it is critical that such policies be developed and implemented in a way that does not undermine patient access to medically necessary care. The purpose of this statement is to review current utilization management policies in use by payers to control the use of cancer drug therapies and to recommend ways to ensure these policies promote rather than hinder patient access to high quality, high-value cancer care.

Payer Strategies to Control the Use of Prescription Drug Therapies

There are several mechanisms that health plans use to control the use of prescription drug therapies. Such utilization management policies include prior authorization, clinical pathways, step-therapy protocols, restrictive formularies, and specialty tiers. In the case of cancer care, another way coverage is restricted is through non-parity of patient cost sharing between oral and infused anticancer drugs. In January 2017, ASCO joined the American Medical Association and 16 other healthcare organizations in establishing Prior Authorization and Utilization Management Reform Principles urging health plans, benefit managers and others to reform utilization management programs.[1] These principles emphasized the importance of clinical validity; continuity of care; transparency and fairness; timely access and administrative efficiency; and alternatives and exemptions in order to ensure patient access to appropriate care while reducing the administrative burden associated with policy compliance.

Considerations in Oncology

Utilization management policies often flow from assumptions regarding the availability of clinically equivalent oncology drugs within the same general class or category. In many cases, oncology drugs do not have substitutes that are both equally effective and less expensive for a given patient. Consequently, policies that attempt to incentivize, force, or coerce patients to

[1] Prior Authorization Reform Workgroup (2017). Prior Authorization and Utilization Management Reform Principles, available at https://www.ama-assn.org/sites/default/files/media-browser/principles-with-signatory-page-for-slsc.pdf.

accept anti-cancer therapy alternatives that are not recommended by their oncologist can threaten both the outcomes for patients and the well-being of their families or caretakers.

ASCO maintains that the most effective means of stewarding limited health care resources is through a value-based health care delivery system. The Society has advanced this concept through several initiatives, including participation in the ABIM Choosing Wisely program, development of a value framework, an extensive performance measurement and quality improvement portfolio, development of a rapid learning system (CancerLinQ), value-based payment reform models, and rigorous clinical practice guidelines. We understand that a value-based payment system is still evolving—and payers may need interim strategies to control cost. However, payers and providers must share the primary goal of delivering high-quality care that is most appropriate for the patient.

ASCO has established the following set of principles as a framework for evaluating the impact of coverage or utilization management policies on the care of patients with cancer:

- Individuals with cancer should have full access to the anti-cancer therapy most appropriate for their disease when used in accordance with current clinical and scientific evidence.
- Cost should not be the primary driver of utilization management policies.
- Utilization management policies should be evidence-based and reflect the most current science and understanding of cancer treatment.
- Utilization management processes should result in timely and clear determinations that are consistent with the health insurer's coverage and other policies.
- Payer cost containment strategies and decision-making processes should be transparent and without conflicts of interest.
- Payers should implement utilization management policies in a way that minimizes administrative burdens on both providers and patients.

Recommendations

A. Prior Authorization Policies Must be Streamlined to Avoid Unnecessary Barriers, Delays in Care, and Other Administrative Burdens

Prior authorization requires patients or prescribers to secure pre-approval as a condition of payment or insurance coverage of the prescribed medication. For example, if one drug in a planned chemotherapy regimen is on a payer's list of products requiring prior authorization, the prescriber often must provide the payer with the full clinical rationale for use of the planned treatment regimen before treatment can proceed.

Payers may use a variety of information sources in making prior authorization determinations, including FDA labeling, clinical practice guidelines, clinical compendia, published clinical literature, and independent medical review, but they often do not disclose the process or basis for prior authorization determinations. Personnel making prior authorization determinations

may not be readily accessible to the prescribing provider and may have limited knowledge in oncology. In addition, the considerable length and complexity of the prior authorization process can cause unnecessary administrative burdens, drawing time and resources away from patient care. Seventy-eight percent of oncology practices responding to the 2016 ASCO Practice Trends Survey cited prior authorization as a significant pressure associated with payers.[2] In a separate survey conducted by the AMA, medical practices indicated that on average they conducted 37 prior authorization requests per week, accounting for approximately 16 hours—or two business days.[3]

Payers can mitigate these barriers to care by limiting the focus of prior authorization requirements to specific areas of concern and by providing an efficient, transparent prior authorization process within a reasonable timeline. Specifically, ASCO recommends that payers:

- Develop and use standardized prior authorization request forms and processes to alleviate the administrative burdens placed on treating oncology teams or practices
- Use a public process by which they determine prior authorization policies for cancer treatment, reflecting the most up-to-date standards of care and including consultation with oncologists
- Restrict prior authorization policies to drugs where specific concerns about inappropriate use and/or undesirable variation exist
- Ensure oncologists make prior authorization determinations in cancer care and provide treating oncologists with direct access to that oncologist to discuss the clinical circumstances as necessary
- Integrate prior authorization processes into electronic health records to support authorization at the points of care, minimizing delays in treatment and administrative burden on providers
- Establish efficient and responsive appeals processes, including 48-hour completion of review/decision on appeals for oncology and expedited review for patients whose clinical circumstances require urgent treatment
- Do not use the appeals mechanisms to compensate for underlying deficiencies in prior authorization policies or process
- Monitor and remedy the predictable, adverse consequences that individuals with cancer may experience from barriers or delays in receiving preferred oncology therapies as a result of prior authorization requirements, including suboptimal clinical outcomes, increases in adverse events, and increases in emergency department visits

[2] American Medical Association (2017). Prior Authorization and Utilization Management Reform Principles, available at https://www.ama-assn.org/sites/default/files/media-browser/principles-with-signatory-page-for-slsc.pdf.

[3] ASCO. The State of Cancer Care in America, 2017: A Report by the American Society of Clinical Oncology. Journal of Oncology Practice. Available online at: http://ascopubs.org/doi/10.1200/JOP.2016.020743.

- Ensure continuity for patients receiving a course of therapy upon enrollment in a health plan to prevent mandatory substitution or interruptions in treatment

B. Utilization Management Policies Must Protect Patient Access to Medically Appropriate Care

A number of utilization management approaches used by payers are of particular concern because they may represent greater likelihood of raising barriers to appropriate care for individuals with cancer. These include step therapy, specialty tiers, restrictive formularies, and non-parity of patient cost sharing for oral cancer drugs. Because cancer is defined increasingly by its molecular signature, such policies—without appropriate safeguards—can impede patient access to individualized, clinically appropriate care for their disease. Payer policies must reflect and be implemented in a way that reflects the evidence of what constitutes appropriate care.

Step Therapy

Step therapy is a utilization management approach that requires patients to use the payer's preferred drug before the payer will cover another drug that may be preferred by the patient and treating physician. Commonly referred to as "fail-first" policies, patients must demonstrate that the payer-preferred product has been unsuccessful before proceeding with the regimen initially recommended in consultation with the treating physician.

The most common use of the phrase "step therapy" refers to policies based solely or in large part on whether two or more drugs fall within the same class or category of drug. The relative cost of drugs within the same category or class is the main driver for classification of "preferred" therapies. Step therapy policies are generally inappropriate in oncology due to the individualized nature of modern cancer treatment and the general lack of interchangeable clinical options. Medically appropriate cancer care demands patient access to the most appropriate drug at the most appropriate time.

A better approach to utilization management is adoption of high-quality clinical pathways or coverage policies based on robust analyses of best clinical practices and existing scientific data. Such clinical pathways or medical coverage policies may recommend or require that oncologists start with one or more drugs prior to using other therapeutic options. Properly designed clinical pathways and coverage policies should adhere closely to the recommendations described previously in this paper, and well-designed policies should not require 100 percent concordance. We typically would not use the phrase "step therapy" to refer to well-designed clinical pathway or medical coverage policies, even if such policies integrate preferences for specific oncology drugs as part of the pathway.

Specialty Specific Tiers

In an effort to limit or discourage use, payers are increasingly placing cancer therapies on the "specialty tier" of their formularies. Placing a drug on a specialty tier shifts a large portion of the cost of care from the payer to the patient, resulting in significant adverse impacts on patient finances, which contributes to medical bankruptcies and disproportionately affects low-income populations.

High coinsurance rates related to specialty tier designation undermine the primary purpose of health insurance— causing cancer patients to face significant financial burdens or to forgo access to life-extending and life-saving drugs. Specialty tiers include drugs that are high cost, molecularly complex, or require special handling, administration and patient education. A drug placed on a specialty tier can result in patient coinsurance payment as high as 30 to 50 percent of the drug's costs. Anti-cancer drugs on a specialty tier may provide the best—or only—treatment option for individual patients. In many cases, there is no lower cost option effective for treatment of a given cancer. Selection of treatment in this scenario depends on the patient's ability to bear enhanced fees, not on what is clinically appropriate.[4]

ASCO recommends against the placement of cancer drug therapies on specialty tiers. Imposing high cost-sharing burdens that target cancer patients, who may have limited treatment options, is fundamentally unfair and counterproductive. The cost-sharing burdens imposed on individuals who require access to anti-cancer drug regimens should not exceed the cost-sharing requirements that otherwise exist under a health insurer's medical benefit.

Restrictive Formularies

The phrase "restrictive formulary" refers to limitations that payers may place on the number of drugs included within a category or class on a payer's drug formulary. Restrictive formulary practices are particularly problematic in oncology because cancer drug therapies often are not clinically interchangeable. The omission of antineoplastic products from formularies whose use are supported by evidence will inevitably interfere with the coverage of life-saving and life-extending therapies for certain cancer patients.

Restrictive formularies may preclude a patient's best option for a successful outcome and should not be a cost containment strategy for cancer drug therapies. Instead, payer formularies should include the full scope of evidence based antineoplastic drugs and rely on high- quality pathways to assure appropriate utilization.

If payers have a value-based process of formulary development, there must be transparency and specialty clinical oversight to ensure mechanisms for how inclusion is valued is clear and

[4] Shankaran V, Ramsey S. Addressing the Financial Burden of Cancer Treatment From Copay to Can't Pay. JAMA Oncol. 2015;1(3):273-274. doi:10.1001/jamaoncol.2015.0423.

medically appropriate. In the event drugs are excluded from formularies due to inferior value, a public appeal system must be in place to allow for consideration of changes as appropriate.

Lack of Parity for Oral Chemotherapy

Another problematic area for cancer patients arises when payers impose higher patient cost-sharing requirements on oral chemotherapy agents covered under the prescription drug benefit than for intravenous or injectable cancer drugs covered under the medical benefit. This circumstance (commonly referred to as the "oral parity" issue) can create financial hardship for patients and, as a result, barriers to appropriate care. Oral cancer drugs may provide significant clinical advantages over the more traditional intravenous and injected forms of cancer medications that may exist to treat a particular type and stage of cancer. In some instances, oral cancer drugs may represent the only treatment option. Ensuring that cancer patients have meaningful access to such oral cancer drugs is an issue of critical clinical importance and not merely an issue of convenience for the cancer patient or health care provider.

ASCO and other members of the oncology community have advocated for oral parity legislation to address this issue and have successfully supported oral parity legislation in a majority of states.[5] These laws aim to ensure equality in patient cost-sharing burdens between oral drugs and intravenously administered drugs. Under oral parity laws, individuals with cancer can access oral cancer drugs under the same general cost-sharing rules that apply to intravenous cancer drugs. These laws also attempt to create safeguards to prevent payers from circumventing the intent of the legislation by reclassifying intravenous drugs or other means. Over forty states have enacted oral parity laws since 2008. Parity should exist in the patient cost sharing for accessing oral and intravenous drugs used in anticancer regimens. Patient copayments, coinsurance, deductibles and other limits for oral anticancer drugs should be reasonable and should be no less favorable for cancer patients than would occur under the policies governing intravenous and injected anticancer drugs.

C. High Quality Clinical Pathways Provide an Appropriate Utilization Management Strategy for Cancer Drug Treatments When Adequate Patient Safeguards Exist

Clinical pathways are evidence-based treatment protocols for delivering quality cancer care for specific patient presentations, including the type and stage of cancer.[6] Payers, institutions, and clinicians use pathways to reduce undesirable variability in care for specified conditions. When

[5] American Society of Clinical Oncology (2016). Parity in Anticancer Drugs: Ensuring Access to Affordable, Evidence-based Treatments, available at http://www.asco.org/sites/new-www.asco.org/files/content-files/about-asco/pdf/2016-oral-parity-issuebrief.pdf.

[6] Zon RT, et. al, American Society of Clinical Oncology Policy Statement on Clinical Pathways in Oncology available at http://jop.ascopubs.org/content/early/2016/01/08/JOP.2015.009134.full.pdf+html.

properly designed, implemented, and updated regularly, clinical pathways can be powerful tools supporting the oncology care team in delivering high-value care.

Clinical pathways have gained increased acceptance in the oncology community in recent years, as pathways have the potential to address costs of cancer care without compromising a patient's clinical need to access certain medically appropriate, but high-cost drugs. A well-designed clinical pathway matches specific clinical diagnoses with evidence-based treatment protocols, allowing patients to access high-cost drugs when medically appropriate. Well-designed clinical pathways also have flexibility to allow providers to treat patients "off-pathway" when warranted clinical circumstances for variation exist. For example, some pathways have the ability for oncologists to identify a contraindication and commence with an off-pathway treatment without undergoing additional prior authorization review.

The potential benefits of clinical pathways for controlling undesirable variability and protecting patient access to evidence-based care are significant. This promise has led ASCO to identify several critical areas for the development and deployment of clinical pathways.[7] However, there are also concerns about the rapid proliferation that has occurred with clinical pathways in oncology, namely that not all pathways are developed and implemented in a high quality and efficient way. The sheer number of competing pathways has created an overwhelming and counterproductive administrative burden for many practicing oncologists. Patients with identical clinical characteristics can experience different clinical pathways based solely on the payer, leading to differences in treatment. These differences can create major practice management difficulties in treatment planning, inventory purchases, and physician time to manage these differences. In November 2016, ASCO released its Criteria for High-Quality Clinical Pathways in Oncology, identifying 15 criteria across three domains (pathway development, implementation and use, and analytics).[8] Although ASCO supports the use of high-quality clinical pathways in oncology as a strategy to promote high-value care, the Society asserts that they should be developed and deployed in accordance with ASCO's criteria, which promote patient protections for clinical pathway development, implementation and use, and analytics.

[7] American Society of Clinical Oncology, Criteria for High-Quality Clinical Pathways available at http://www.asco.org/sites/newwww.asco.org/files/content-files/blog-release/documents/2016-ASCO-Criteria-High-Quality-Pathways.pdf.

[8] American Society of Clinical Oncology, Criteria for High-Quality Clinical Pathways available at http://www.asco.org/sites/newwww.asco.org/files/content-files/blog-release/documents/2016-ASCO-Criteria-High-Quality-Pathways.pdf.

Conclusion

In the interest of supporting high-value, high-quality care, ASCO supports policies that promote full access to the most appropriate oncology drug regimens at the most appropriate time for patients with cancer. We understand and share concerns about cost and have engaged in a wide range of efforts to ensure appropriate use of cancer therapies. Any strategies to address cost, however, must first protect patient access to the most appropriate therapy for treatment of their cancer. Although drugs are a costly component of cancer care, ASCO also recognizes that other treatment modalities may be costly and at times, over-utilized. We encourage the same thoughtful evidence-based policy approach to all healthcare coverage decisions. In general, well-designed high-quality pathways should be the first choice of payers in their efforts to assure appropriate utilization of anti-cancer drugs and delivery of high value care.

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