

Advancing
Immuno-Oncology
in the
Community
Setting



ICLIO

INSTITUTE FOR CLINICAL
IMMUNO-ONCOLOGY

AN INSTITUTE OF

ACCC

Association of Community Cancer Centers

ICLIO Advisory Committee

CHAIR

Lee S. Schwartzberg, MD, FACP

Chief, Division of Hematology Oncology
Professor of Medicine

The University of Tennessee; The West Clinic, PC

Jennie R. Crews, MD, FACP

Medical Director, Cancer Services PeaceHealth
St. Joseph Medical Center

Steven D'Amato, BSPHarm, BCOP

Executive Director

New England Cancer Specialists

David S. Ettinger, MD, FACP, FCCP

Alex Grass Professor of Oncology

Sidney Kimmel Comprehensive Cancer Center
at Johns Hopkins

Johns Hopkins University School of Medicine

Niesha Griffith, MS, RPh, FASHP

Administrator, Oncology Pharmacy and
Infusion Services

The Arthur G. James Cancer Hospital

The Richard J. Solove Research Institute at
The Ohio State University

Sigrun Hallmeyer, MD

Chair, Cancer Committee and Medical Director,
Survivorship Program

Advocate Lutheran General Hospital

Director, Oncology Specialists Research Institute
Oncology Specialists, S.C.

Linda House, RN, BSN, MSM

President

Cancer Support Community

John M. Kirkwood, MD

Usher Professor of Medicine, Dermatology &
Translational Science

Director, Melanoma and Skin Cancer Program

University of Pittsburgh Medical Center

Cathy Schott, RN, BSN, CCRC

Immunotherapy Program Coordinator

Wheaton Franciscan Healthcare

Michael Seiden, MD, PhD

Chief Medical Officer

McKesson Specialty Health

US Oncology Network

Dan Todd, JD

Principal

Todd Strategy

Association of Community Cancer Centers

Christian Downs, JD, MHA

Executive Director

Amanda Kramar

Director, Provider Education

Lorna Lucas, MSM

Senior Manager, Provider Education

EDITORS

Monique J. Marino

Manager, Publications

Amanda Patton

Manager, Communications

Contributors

William T. McGivney, PhD

Principal

McGivney Global Advisors

Jake Guinto, PhD

Senior Consultant

McGivney Global Advisors

Advancing Immuno-Oncology in the Community Setting

TABLE OF CONTENTS

An Introduction to Immuno-Oncology	2
The Institute for Clinical Immuno-Oncology (ICLIO)	2
• Results from the 2014 ACCC-Member Needs Assessment Survey	
FDA-Approved Immuno-Oncology Therapies	4
• Treatment for Melanoma Patients	
• Treatment for Lung Cancer Patients	
• Treatment for Renal Cell Carcinoma Patients	
Immuno-Oncology Therapies in Development	4
Immuno-Oncology Response Patterns	5
Immune-Related or Mediated Adverse Events	5
Programmatic & Implementation Considerations	6
• Identifying an “Immuno-Oncology Champion”	
• Coverage & Reimbursement Challenges	
• Coverage & Reimbursement Strategies	
Care Coordination	9
Distress & Quality of Life	10
ICLIO Programs & Resources	11
Growing ICLIO	13

An Introduction to Immuno-Oncology

For decades, clinical science has sought to better understand the human immune system in order to manipulate that system to fight invasive foreign cancer cells. Cancer remains a formidable enemy with its virulent replication of cells and its own subtle, harmful manipulation of the immune system. In recent years, however, science has begun to tease apart the insidious workings of cancer cells and their negative influence over the immune system. Indeed, the most prominent of the immunologic therapeutic advances is the recent introduction of agents commonly referred to as “checkpoint inhibitors” (e.g., ipilimumab, nivolumab, pembrolizumab). Tumor cells express “checkpoint proteins” on their cell surfaces that dampen the immune system response to the antigenic proteins cancer cells also express. The “checkpoint inhibitors” target and inhibit the activity of the “checkpoint proteins,” reactivating and enhancing the immune response against the tumor. These checkpoint inhibitors reflect a maturation of immunotherapy over many, many years of discussion, research, and clinical application. In the last five years, the oncology community has seen the introduction of vaccines and checkpoint inhibitors, as well as the ongoing development of a robust pipeline of immunotherapeutics, including emerging combination therapies. Accordingly, immuno-oncology has become the fourth pillar of oncology treatment.

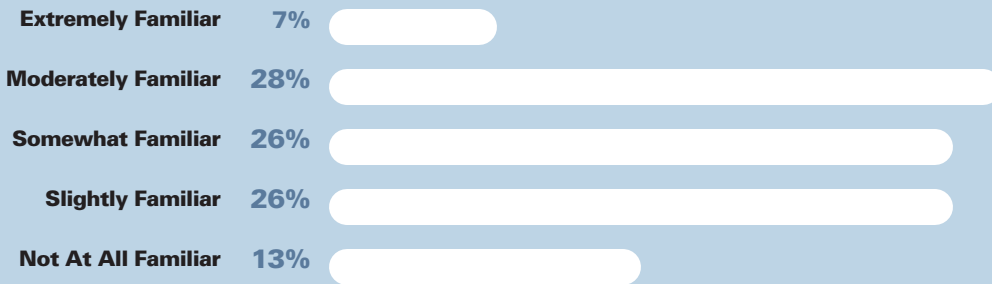
The Institute for Clinical Immuno-Oncology (ICLIO)

The Association of Community Cancer Centers (ACCC) recognized the critical need to translate advancements in cancer immunotherapy—through specific immuno-oncology biologics—into practical applications. To meet this need, ACCC created the Institute for Clinical Immuno-Oncology (ICLIO). Today ICLIO is helping to bring these therapies from benchside to bedside by addressing issues, challenges, and implementation strategies for the multidisciplinary cancer care team. Through ICLIO, ACCC provides members and the cancer community at large with a forum and the essential knowledge and support needed to develop a community centered on transformative care. To shape ICLIO’s vision and guide its approach, ACCC conducted a needs assessment survey. The survey, disseminated in December 2014 in collaboration with the National Comprehensive Cancer Network (NCCN), had more than 1,000 clinician respondents, self-identified as physicians (63 percent), nurses (15 percent), pharmacists (6 percent), physician assistants or nurse practitioners (5 percent), and other clinicians (11 percent). Analysis of survey results identified five strategic areas of need around these new immuno-oncologic agents:

- 1 Clinical Optimization (a basic understanding of the state of the science)
- 2 Coverage & Reimbursement
- 3 Management Best Practices (operational opportunities, challenges, and solutions)
- 4 Patient Access & Advocacy (patient-specific needs, benefits, and risks)
- 5 Training & Development (resources to help providers keep current with advances in immuno-oncology)

When asked about their familiarity with immuno-oncologic agents, a plurality responded that they were either “not at all familiar” or only “slightly familiar” with these agents. Only 7 percent reported being “extremely familiar” with these agents (see Figure 1, page 3).

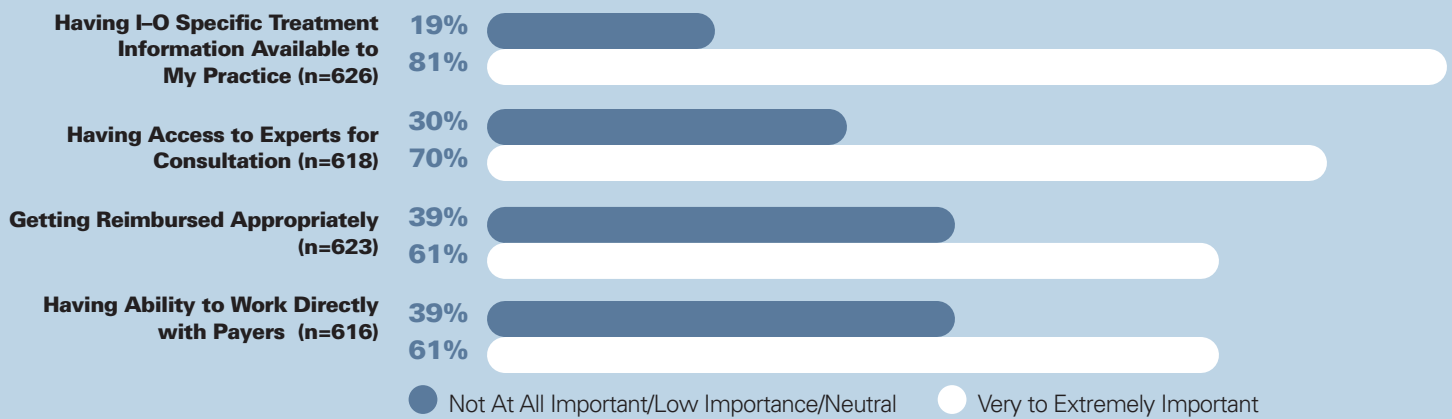
FIGURE 1 | Familiarity of the Concept of Immuno-Oncology, Immuno-Oncology Drugs and Biologics Coming to Market, and Potential Clinical Applications of These Agents (n=752)



At least two-thirds of survey respondents categorized the need for clinical information and updates, coverage and reimbursement changes, and practice and operational assistance and planning to ensure patient access to immunotherapies as “very to extremely important.” When queried on the most challenging areas for clinicians in achieving optimal use of immuno-oncology therapy, responses were consistent with the two-thirds majority views cited above. Finally, the majority of survey respondents identified the following practice needs as “very to extremely important”:

- Immuno-oncology specific treatment information available to my program
- Access to experts for consultation
- Adequate reimbursement
- Ability to work directly with payers (see Figure 2, below).

FIGURE 2 | Immuno-Oncology Issues Important to a Practice or Cancer Program



The needs assessment survey findings, input from a national advisory committee composed of key opinion leaders, and findings from a number of focus groups—coupled with the Association of Community Cancer Centers’ programmatic, public policy, and clinical expertise—helped lay the foundation for ICLIO’s multidisciplinary approach. The provider-identified five areas of need (domains) formed the ICLIO framework and provided guidance for the development of ICLIO’s comprehensive programmatic and clinical immuno-oncology resources.

This publication explores the work of ICLIO to date, with a focus on the introduction of immuno-oncology therapies, including the opportunities and challenges facing clinicians, administrators, payers, biopharmaceutical companies, and, most importantly, the patients we serve.

FDA-Approved Immuno-Oncology Therapies

Patient interest in these new immuno-oncologic agents, as well as their expensive price tags, makes it critical for providers to keep up-to-date on when these agents enter the market. This knowledge allows cancer programs to educate staff and patients about emerging immuno-oncology treatments and to develop effective implementation strategies—ensuring both patient access and adequate reimbursement. From the clinical perspective, there is the need to understand differences in patients' responses to immuno-oncology therapy, to understand how to manage toxicities, and to educate all members of the multidisciplinary care team, the broader provider community, and patients and caregivers.

IMMUNO-ONCOLOGY FOR MELANOMA PATIENTS

In 2011 the U.S. Food and Drug Administration (FDA) approved ipilimumab, a CTLA-4 inhibitor, for the treatment of patients with unresectable or metastatic melanoma—a first-line therapeutic that dramatically improved survival. The approval of ipilimumab was followed by FDA approval in melanoma for pembrolizumab and then approval for nivolumab for patients with unresectable or metastatic melanoma with disease progression. These latter immuno-oncologic agents exhibited a more favorable toxicity profile with analogous benefit. On October 1, 2015, the FDA approved the first checkpoint inhibitor combination: the first-line use of nivolumab with ipilimumab in patients with unresectable or metastatic melanoma.

IMMUNO-ONCOLOGY FOR LUNG CANCER PATIENTS

On March 4, 2015, the FDA approved nivolumab to treat patients with metastatic squamous non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy. That same year on October 2, 2015, the FDA granted approval for pembrolizumab to treat patients with metastatic NSCLC whose disease had progressed after other treatments and with tumors that express a protein called PD-L1. Pembrolizumab was approved for use with a companion diagnostic, the PD-L1 IHC 22C3 pharmDx test, the first test approved to detect PD-L1 expression in NSCLC tumors. A few days later, on October 9, 2015, the FDA approved nivolumab to treat NSCLC, including non-squamous cancers, that had progressed after platinum-based therapy.

IMMUNO-ONCOLOGY FOR RENAL CELL CARCINOMA PATIENTS

On November 23, 2015, the FDA approved nivolumab for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy. Approval was based on activity in patients who had received one or two anti-angiogenic regimens. In this setting, nivolumab showed improved median overall survival (OS) compared to another drug in a randomized trial recently reported in the published literature.¹ Toxicity appears consistent with prior reports for nivolumab as monotherapy.¹

IMMUNO-ONCOLOGY THERAPIES IN DEVELOPMENT

Immuno-oncologic agents are presently in development for a host of tumor types in the following cancers:

- Bladder
- Breast
- Colorectal
- Esophageal
- Head & Neck
- Hepatocellular
- Leukemia
- Lung
- Lymphomas
- Melanoma
- Ovarian
- Pancreas
- Prostate

In addition to nivolumab's indication as a single agent to treat patients with advanced RCC, nivolumab is being studied in combination with ipilimumab to treat patients with metastatic RCC. Preliminary findings of this combination show impressive response rates.^{2,3}

Among the new indications, anti-PD1s have shown significant patient benefit in head and neck cancers. In a study by Cohen and colleagues, pembrolizumab demonstrated a clinically significant 24.8 percent overall response rate (ORR) in patients with recurrent or metastatic squamous cell carcinoma of the head and neck.⁴ This ORR basically doubled the best response rates achieved in the past.⁴ Overall, 56 percent of patients had a decrease in the size of tumor lesions and, in 86 percent of patients who responded, these responses were durable.⁴ Consistent with previous studies, pembrolizumab was well tolerated.⁴

Immuno-Oncology Response Patterns

One challenge with immuno-oncologic agents: response patterns to these agents may differ from traditional response patterns seen with cytotoxic therapies. Specifically, the unique mechanism of action of checkpoint inhibitors can result in the following response characteristics, which can influence clinical decision-making:

- Duration for an anti-tumor response may take longer.
- Clinical response to immunotherapy may become apparent only after a period of “pseudoprogression” when immune cell infiltration can manifest as new lesions or continued growth of old lesions that are mistaken for disease progression.
- Discontinuation of immunotherapy may not be appropriate in some cases until progressive disease is confirmed.
- Allowance for “clinically insignificant” progressive disease (e.g., small lesions in the presence of other responsive lesions) is recommended.
- Durable stable disease may represent anti-tumor activity.

Given the variable response patterns of immuno-oncologic agents, clinicians recognized that conventional Response Evaluation Criteria in Solid Tumors (RECIST) may not provide a complete assessment of immunotherapy response. Accordingly, clinicians adopted a set of immune-related Response Criteria (irRC) to better assess the actual response patterns with immuno-oncologic agents. (While a fuller description of irRC is beyond the scope of this publication, more information is available on the ICLIO website at: acc-iclio.org/resources/assessing-immunotherapy-response-why-irrc-matters.)

Immune-Related or Mediated Adverse Events

Patients on immuno-oncologic agents can potentially experience treatment-related adverse events (AEs), i.e., immune-related adverse events (irAEs). These irAEs can differ in patients taking checkpoint inhibitors versus AEs traditionally seen in patients treated with cytotoxic agents. Clinicians must recognize that patients on immuno-oncologic agents have an increased likelihood that certain AEs likely represent manifestations of an activated immune system, and that the treatment for this type of AE is most likely attenuation or temporary suppression of immune system activity. Attenuation can be achieved by use of steroids, infliximab, or other medications. Further, withholding of the therapeutic immuno-oncologic agent may be necessary; in serious and life-threatening situations, permanent discontinuation of the immuno-oncologic agent may be recommended. Specific to ipilimumab, the following irAEs, among others, may occur:⁵

- Dermatitis can be life-threatening to the point of requiring permanent discontinuation of the biologic.
- Colitis and enteritis may occur with inflammation anywhere in the GI tract, with diarrhea a common irAE; most patients likely will respond to symptomatic management or high-dose steroids with a long taper.
- Endocrinopathies may occur but are relatively infrequent.
- Liver enzymes may become elevated and may be associated with symptoms of hepatotoxicity; all patients should meet specified liver function test (LFT) criteria before each dose of a checkpoint inhibitor.
- Pancreatitis can occur with amylase/lipase elevation and abdominal pain low and out of proportion to elevation of lab tests.
- Uveitis may occur with change in vision.
- Neuropathies are rare.

The anti-PD1s (nivolumab and pembrolizumab) have a similar spectrum of irAEs but with lower frequencies of grade 3-4 events. Symptomatic pneumonitis is more common with PD-1 antibodies, occurring with a frequency of one to two percent; thyroiditis is also more common. Grades 3-4 colitis are rare with anti-PD1s (one percent); however, when colitis occurs, it generally has the same prolonged course as seen with ipilimumab.⁶ (More information on irAE management and protocols is available online at: acc-iclio.org/resources/a-different-way-of-thinking-putting-irrc-into-practice.)

CALL TO ACTION: To meet the challenges related to response patterns and immune-related or mediated adverse events, cancer programs should bring together a core group of physician leaders with expertise and experience in immuno-oncology. Further, because immuno-oncologic agents have adverse event profiles that are distinct from traditional chemotherapeutic agents and from other commonly-used biologics, cancer program staff who triage patient phone calls need to be educated about the potentially serious adverse events that require immediate attention. Practice protocols need to be updated to account for patients treated with immuno-oncologic agents and management pathways need to be revised to include potential immune-related adverse events.

Programmatic & Implementation Considerations

Through direct interactions with clinicians and administrators at cancer programs and practices that reflect the diverse ACCC membership, ICLIO has identified key administrative challenges in immuno-oncology implementation, including:

- Keeping up-to-date with a vast amount of new research, indications, and combination therapies, and ensuring that all stakeholders are properly educated about this information.
- Navigating coverage and reimbursement issues.
- Providing financial advocacy services that are patient-focused, while also ensuring adequate reimbursement and safeguarding the cancer program's financial viability.
- Responding to patient issues related to immuno-oncologic agents, for example proper triage, appropriate patient and caregiver education, and follow up and monitoring of adverse events.
- Developing efficient pharmacy processes (e.g., off-label use, inventory, dosing alerts).

IDENTIFYING AN "IMMUNO-ONCOLOGY CHAMPION"

Immuno-oncologic agents have greatly enhanced the treatment options of patients diagnosed with melanoma, non-small cell lung cancers, and renal cell carcinoma, as demonstrated by how rapidly these agents have received FDA approval and inclusion in the NCCN Drugs and Biologics Compendium. This pace of advancement is likely to accelerate with respect to new approved uses in new lines of therapy, in additional tumor types, and in combinations with other biologics and drugs. In other words, administrators and clinicians should understand that the currently marketed immuno-oncology products represent the "tip of the iceberg." Pharmaceutical pipelines include a number of novel immuno-oncologic agents. With some predicting that the next five years may bring new approvals, new indications, and/or new combinations on a monthly basis, staying up-to-date and current on immuno-oncology is critical for clinicians and cancer programs. One strategy for doing so is to identify an "immuno-oncology champion" to serve as the immunotherapy point person for gathering information, answering questions, and educating staff.

COVERAGE & REIMBURSEMENT CHALLENGES

Another key stakeholder to join the immuno-oncology dialogue will be the payers. Just as clinicians are challenged to understand and manage rapidly evolving scientific advancements and clinical applications of immuno-oncologic agents, public and private payers are similarly challenged in keeping their coverage policies current with approved and recommended indications. While all major payers have written policies that link coverage to NCCN Category 1 and Category 2A recommendations, the coverage policies of several major national payers are not always up-to-date with the publication of major research study findings and NCCN recommendations. For example, while NCCN recommended the use of nivolumab in second-line NSCLC in June 2015, payers were slow to issue any affirmative coverage policy for this indication. Given that payers may not be keeping their coverage policies current, providers must expend additional time and resources to ensure immuno-oncology agents will be adequately reimbursed and to mitigate patient uncertainty about access to these agents in the face of serious and life-threatening disease. Unfortunately, providers and patients are likely to face increased coverage and reimbursement challenges as the introduction of new immuno-oncologic agents accelerates.

Medicare coverage of immuno-oncologic agents presents similar challenges. For example, one major academic cancer center reports that, as of this writing, its Medicare Administrative Contractor (MAC)

lacks any specified coverage policy for the anti-PD1s. Conversely, Wisconsin Physicians Service (WPS) has been an exemplary MAC, keeping current with FDA approvals and NCCN recommendations that are supported by major published studies.

Additionally, another challenge in the coverage and reimbursement space revolves around the fast-paced introduction of immuno-oncologic agents, specifically the issue of lag time in assigning specific J-codes for these new agents. The assignment of a J-code to a specific agent helps ensure accurate reimbursement for that agent. In the absence of a specified J-code, reimbursement can often be insufficient.

Finally, payers have expressed concerns over the potentially staggering cost impact of wide adoption of immuno-oncologic agents, and are seeking better evidence defining those patient populations that will clearly benefit from these agents. This, in turn, has raised a controversial and widely-discussed issue: identifying biomarkers for I-O therapies and the actual (or potential) role for PD-L1 overexpression as a biomarker, the differing cut-off levels considered as overexpression, and the substantial functional heterogeneity of tests available.

Taken together, these payer issues color almost any conversation about the substantial benefit to be derived from checkpoint inhibitors and other immuno-oncologic agents with some clinicians expressing serious concern that payer policies may diminish provider autonomy and authority and have an adverse effect on patient access to life-saving immunotherapies.

COVERAGE & REIMBURSEMENT STRATEGIES

All of the challenges cited above require providers to take proactive steps to ensure the financial stability and viability of their cancer program while acquiring these new I-O agents so that the appropriate patients have access to these therapies. ICLIO offers a variety of practical resources for cancer programs and practices to develop programmatic strategies to support these efforts. For example, one major academic cancer center involved with the ICLIO community shared its seven-step strategy for integrating new immuno-oncologic agents into practice:

- 1** Have a process in place for appropriate financial management and billing until a J-code is assigned.
- 2** Identify a financial or reimbursement staff person to be the “immuno-oncologic lead.” This individual should be an expert in the nuances of manufacturer patient assistance programs and co-pay foundations to optimize reimbursement and patient support.
- 3** Have sufficient financial advocacy support. While needs will vary depending on the size of the program and the patient population served, robust patient financial advocacy support is critical. Financial counselors and/or advocates generally pay for themselves many times over. Tracking metrics for internal analyses support the return on investment (ROI) for this staff role.
- 4** Require pre-certification for on-label use and enroll all patients in manufacturer-sponsored programs for benefits investigation and/or co-pay support.
- 5** Develop immuno-oncology policies and processes for off-label uses. Require pre-certification for all off-label uses. Enroll all patients in manufacturer-sponsored programs and/or benefits investigation, appeals, and potential medication replacement.
- 6** Ensure that patients are made aware of risks and benefits, including financial challenges. Require patients to sign an advanced beneficiary notice or notice of non-coverage.
- 7** Be prepared for patients who may be willing to pay out-of-pocket for immuno-oncologic therapies.

(See case study on page 8)

REIMBURSEMENT CHALLENGES: A CASE STUDY

A high-volume academic cancer center active in the ICLIO community shared the following challenges related to coverage and reimbursement for anti-PD1 therapy. As of October 2, 2015, the cancer center had treated 128 patients with nivolumab for 10 different tumor types.

The leading tumor types treated were:

- Renal cell carcinoma (28 percent)
- Metastatic melanoma (25 percent)
- Lung cancer (24 percent).

These high-volume indications were followed by non-Hodgkin lymphoma, bladder cancer, prostate cancer, head and neck cancer, Merkel cell carcinoma, and porocarcinoma. For the 128 patients treated with immuno-oncologic agents, there were no financial write-offs; 47 patients received drug replacement assistance from the biopharmaceutical company and 14 patients received co-pay assistance.

As of October 2, 2015, the cancer center had treated 20 patients with pembrolizumab. Most indications (90 percent) were for metastatic melanoma; other indications were for lung cancer, cholangiocarcinoma, and renal cell carcinoma.

This institution is proactively monitoring the accelerated use of immuno-oncologic agents as monotherapy and in combination across tumor types and lines of therapy, including potentially in the adjuvant setting. The cancer center remains concerned that payers will not keep up with the rapidly increasing knowledge base that supports this fourth pillar of oncology treatment. Specifically, there is concern that there will be increasing use of step therapy specifications as the number of marketed anti-PD1s and anti-PD-L1s increases.

Care Coordination

To provide optimal care, a care coordinator with expertise and experience in immunotherapy must be an active participant across functional areas. This individual will serve as the primary contact for patients and their families, and his or her role will include:

- **Organizing and pre-screening patients for immuno-oncology regimens.** Including, but not limited to, interviewing the patient and reviewing the medical record for pre-existing conditions (e.g., autoimmune disease) or prior adverse events. Any concerns detected will be communicated to the treating physician. For patients with pre-existing conditions or prior AEs who proceed with immuno-oncology treatment, special precautions will be followed.
- **Connecting patients with a financial advocate for early intervention and billing explanations.** Patient financial issues must be identified and carefully considered to avoid unnecessary worry for the patient and caregiver(s). Private payer pre-determinations must be conducted and out-of-pocket payments evaluated and estimated. Out-of-pocket costs must be addressed through all available means, including patient assistance programs, charitable foundations, etc.
- **Managing patient care in terms of follow-up, tests and procedures, consultations, etc.** Continual communication is important. There must be regular follow-up calls by clinical staff to assess for irAEs. If AEs occur, daily follow-up may be needed for ongoing clinical evaluation. Patients require ongoing monitoring of response to medications, including laboratory monitoring and/or in-person office visits. Patients (and caregivers) must understand the general circumstances that warrant an emergency room visit, if the AE is high-grade or life-threatening.
- **Educating staff and patients and their families on potential adverse events and irAEs for timely intervention.** Patient education and information exchange must be ongoing. Patients must be furnished with wallet cards and/or symptom logs. Accurate reporting of AEs by patients is critical.

Care coordination continues after treatment. Patients should be encouraged to keep long-term follow-up appointments. Assessment for new irAEs (late effects) should occur at these long-term visits for continued assessment and management. Long-term issues are crucial given the long, durable responses with ongoing immune response in patients.

Distress & Quality of Life

Today's challenging care delivery systems and processes bring new challenges for cancer patients, including:

- Anxiety and worry while waiting for pre-certification approval.
- The need for providers and patients to take into account a payer's preferred agents when making treatment decisions.
- Stress and concern about payer-imposed cost sharing, including high co-pays and high deductibles.

Recent publications report that 40 percent of patients with cancer live with moderate to high levels of psychosocial stress; 47 percent of patients live with a high degree of financial distress; and 36 percent of patients with cancer do not return to work.⁷ Many patients live with chronic toxicities requiring follow-up care.⁷

Providers should manage patient distress through systematic screening and follow-up that identifies the causes of ongoing stress and strategies for reducing these stressors. There is evidence that stress levels can be substantially reduced with even single interventions, such as a follow-up call to talk with the patient.⁷ In today's complex cancer care delivery system, it is critical that all stakeholders work to alleviate some of the burden from patient(s) and caregiver(s) to help them live longer, healthier lives.

ICLIO Programs & Resources

ICLIO is a participatory, collaborative community built around five strategic domain areas:

- 1 Clinical understanding and optimization
- 2 Coverage and reimbursement
- 3 Management and operations opportunities and challenges
- 4 Patient needs, benefits, and risks
- 5 Keeping up with immuno-oncology advances and challenges through education, information, and training.

In 2015 ICLIO developed a number of programs and resources to help the multidisciplinary cancer care team prepare for and meet the challenges and opportunities presented by immuno-oncology—the fourth pillar of oncology treatment. These activities include, but are not limited to, publishing e-Newsletters on pressing immunotherapy topics, interviews with leading experts, e-Courses that educate and explore “real world” clinical practice considerations, and the first ICLIO Conference. Below are some of the programs and resources available at acc-iclio.org.

e-Newsletters

These monthly newsletters cover clinical optimization, patient access and advocacy, reimbursement and coverage, and management and administration of immuno-oncology therapies, including:

June 2015

- Assessing Immunotherapy Response—Why irRC Matters
- A Different Way of Thinking: Putting irRC into Practice
- Helping Your Patient Understand I-O

July 2015

- How Immuno-Oncology is Leaving its Mark in the Treatment of Lung Cancer
- Commentary From the Field: Payers as Key Players in the Access and Availability of Immuno-Oncology Therapy
- New Kids in Town: An Update on PD-1 and PD-L1 Checkpoint Inhibitors

August 2015

- Immuno-Oncology 101: Basics of Checkpoint Inhibitors
- The Financial Burden and Cost of Cancer Care, A Physician’s Perspective

September 2015

- Immuno-Oncology High Dollar Process Tool
- Scholar Spotlight: The Role of the Oncology Social Worker
- Perspectives From the Field: Immunotherapy for Lung Cancer
- From Benchside to Bedside: The Rapid Ascent of Immuno-Oncology Agents, Connecting the Administrative Immuno-Oncology Dots

October 2015

- ICLIO Conference Snapshot

(See e-Courses on page 12)

e-Courses

ICLIO presented the following e-Courses to help educate the multidisciplinary cancer care team about cancer immunotherapies and related “real world” challenges:

July 2015

- Immune-Related Response Criteria: Variations in Immuno-Oncology Response Patterns and Implications for Treatment
- Immunotherapy in Non-Small Cell Lung Cancer

August 2015

- Navigating Immuno-Oncology Coverage & Reimbursement

September 2015

- Immuno-Oncology Management Best Practices
- Managing Adverse Events Associated with Immuno-Oncology Agents

October 2015

- Managing Patient Expectations

REFERENCES

- 1 Motzer RJ, et al. Nivolumab versus everolimus in advanced renal cell cancer. *N Engl J Med.* 2015; Published online Sept. 25, 2015.
- 2 Hammers HJ, et al. Phase I study of nivolumab in combination with ipilimumab in metastatic renal cell carcinoma (mRCC). *J Clin Oncol.* 32:5s, 2014 (suppl; abstr 4504).
- 3 Hammers HJ, et al. Expanded cohort results from CheckMate 016: A phase I study of nivolumab in combination with ipilimumab in metastatic renal cell carcinoma (mRCC). *J Clin Oncol.* 33, 2015 (suppl; abstr 4516).
- 4 Cohen EEW, et al. A phase III randomized trial of pembrolizumab (MK-3475) versus standard treatment in patients with recurrent or metastatic head and neck cancer. *J Clin Oncol.* 2015; 33:suppl, abstract TPS6084.
- 5 Postow MA, et al. Immune checkpoint blockade in cancer therapy. *J Clin Onc.* 2015;33(17):1974-1982.
- 6 Weber J. Review: Anti-CTLA-4 antibody ipilimumab: case studies of clinical response and immune adverse events. *The Oncologist.* 2007;12:864-872.
- 7 House L. Providing 360 degree patient support: financial access, patient assistance and patient expectations. Presentation ICLIO Conference, Oct. 2, 2015.

Growing ICLIO

ICLIO proactively seeks new ideas on how to best move forward across the Institute's five strategic domain areas. Engaged ICLIO participants have already offered ideas for the future evolution of the Institute and now we invite your input on future activities and programs that will help ACCC-member programs meet "real world" challenges, opportunities, and applications in immunotherapy. Opportunities for future participation in ICLIO include:

- Comprehensive educational modules to prepare multidisciplinary team members.
- Ongoing identification and communication of key clinical practice issues to optimize patient management.
- Design and development of novel, impactful clinical education and information.
- Development of a clinical agenda for the Institute as a whole.
- Development, identification, and dissemination of immuno-oncology best practices.
- Identification of and strategies for addressing coverage and reimbursement issues, including tracking and communicating payer coverage policies regarding immunotherapy.
- Development of resources to ensure patient access to immuno-oncologic agents, to improve provider and patient interactions, and to provide effective financial advocacy services.
- Ongoing collaborative arrangements with key patient advocacy organizations.
- Research the feasibility and usefulness of brief immuno-oncology training rounds or preceptorships with immuno-oncology experts in both the academic and community setting.
- Development of strategies to enhance the autonomy and authority of clinicians and ensure patients access to and availability of innovative immunotherapies.

In founding ICLIO, the Association of Community Cancer Centers seeks to anticipate and address challenges that might delay patient access to and availability of immuno-oncologic agents.

Learn more at acc-iclio.org

Association of Community Cancer Centers

This publication is a benefit of membership.



11600 Nebel Street • Suite 201 • Rockville, MD 20852
301.984.9496 • acc-cancer.org

acc-icl.io.org



ICLIO

INSTITUTE FOR CLINICAL
IMMUNO-ONCOLOGY

ICLIO is made
possible by a
charitable donation
from
Bristol-Myers
Squibb.



Bristol-Myers Squibb