

Facilitating Access to Cancer Immunotherapies

In October 2018, the Association of Community Cancer Centers (ACCC) hosted a pre-conference workshop at its 35th National Oncology Conference to review how oncology pharmacists can best respond to rapid changes in the oncology environment. The following summarizes key takeaways from a session on effective integration of immuno-oncology (IO) into resource allocation and reimbursement processes.

Budget and Operational Considerations in Care Coordination

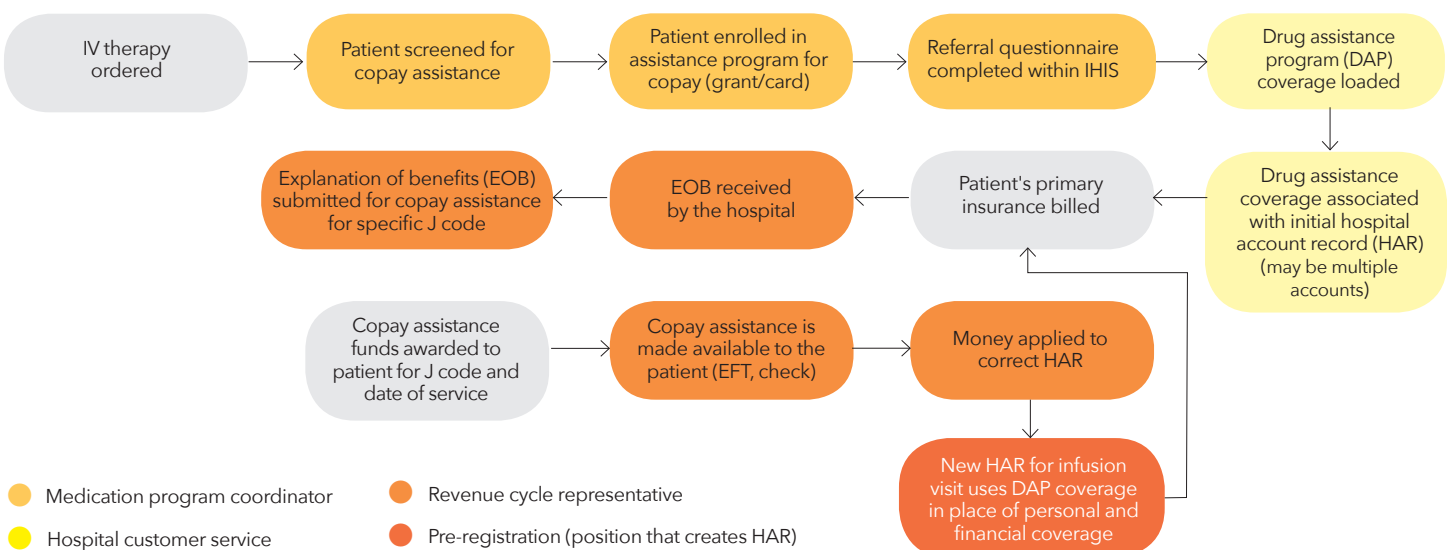
Responsibilities of the multidisciplinary cancer care team include, but are not limited to, entering medication orders; documenting progress reports (e.g., therapy rationale, laboratory results, and biomarkers ordered); and educating patients on their therapeutic options, side effects, and costs. With increasing approvals for immunotherapy in more oncology disease states and new approvals for combination therapies, oncology pharmacists play a key role on this team. In addition, many multidisciplinary oncology teams have grown to include patient advocates, financial navigators, and reimbursement specialists to help patients access these new and emerging therapies. When planning for immunotherapy integration in community cancer programs, Una Hopkins, RN, FNP-BC, DNP, Administrative Director, Cancer Program at White Plains Hospital, Center for Cancer Care, stressed the importance

of advance communication with hospital administrators about the value of immunotherapies. Notably, budget decisions can also affect patient selection, opportunities to place patients on a clinical trial, and resource allocations (such as refrigerator space). For instance, the implementation of an IO program in a community cancer program is likely to increase the authorization/denial workload and place additional demands on refrigerator space if patients are in receipt of compassionate drug assistance. Dr. Hopkins emphasized the importance of planning for the impact of immunotherapies on pharmacy and nursing budgets and revenue cycles, as well as exploring practical issues, such as whether to treat patients through exception/non-formulary arrangements.

The Role of Reimbursement Specialists in Cancer Immunotherapies

Sarah Hudson-DiSalle, PharmD, RPh, Oncology Pharmacy Manager, Medication Assistance Program and Reimbursement Services at the Arthur G. James Cancer Hospital and Wexner Medical Center, Ohio State University Department of Pharmacy, addressed oncology pharmacy reimbursement workflow issues in an academic setting. The biggest change in workflow, she said, has involved proactively screening patients for financial assistance before they start therapy and incorporating financial navigation as part of the treatment planning process flow (Figure 1).

Figure 1. Copay Assistance Workflow



What's the timeframe for determination decisions?

Dr. Hudson-DiSalle noted that if the request is on-label, most payers take between 3-14 days for an authorization decision and pharmaceutical manufacturers take 3-5 business days to respond to medical assistance requests. If the request is off-label, at a minimum, it takes approximately 2 weeks for payers to respond, and another 2 weeks for manufacturers to respond. She emphasized that the oncology pharmacy at the James Cancer Hospital tries to communicate to providers that there is a protracted turnaround time for receiving a determination about off-label therapies.

At the James Cancer Hospital, the reimbursement specialist team is responsible for collating clinical materials in one package to support the authorization process and interacting with payers to secure authorization for treatment. In order to interact effectively, this team is extensively prepared with knowledge about payer and Medicare policies pertaining to immunotherapies (e.g., compendia support, local and national coverage determinations, and evidence-based guidelines). To ensure that patients are not burdened with unnecessary costs of therapy, medication assistance program coordinators (MAPCs) inform patients about anticipated copays prior to therapy, screen and identify patients likely to need assistance, identify foundation funding resources for patient assistance, and enroll eligible patients upfront. This proactive enrollment helps to reduce delays in access to therapy should a patient be denied coverage by their insurance for the use of an immunotherapy agent. MAPCs at the James Cancer Hospital have also developed a process to identify opportunities whereby free medication and/or copay assistance may be available.

Off-Label Medication Considerations

Many clinicians wish to use emerging therapies, including combination regimens that are not yet FDA approved, but nonetheless supported by substantive clinical evidence. However, as Dr. Hopkins noted, much of this evidence is at the phase 1 level—indeed, immunotherapy approvals are increasingly based on phase II and limited phase III data. While these clinical data might be included in compendia, this information rapidly becomes outdated, and clinical policies that payers use to authorize treatment often lag behind clinical evidence. Dr. Hudson-DiSalle cautioned that clinical policies frequently

require medication eligibility restrictions beyond the label and that additional criteria be met in order to assure reimbursement. For example, Anthem's clinical policy for nivolumab requires that a current Eastern Cooperative Oncology Group (ECOG) score 0-2 be met. Therefore, providing access to off-label therapies involves considerable upfront discussion with patients and providers about therapeutic and financial risks and a strategy to explore manufacturer assistance.

What do you do when a physician requests an immunotherapy agent that is considered off-label?

At the James Cancer Hospital, the off-label process involves reviewing the evidence for off-label use and filing a predetermination request to the payer or, if the payer is Medicare, requires the patient to sign an Advance Beneficiary Notice (ABN). The MAPC will then explore pharmaceutical manufacturer assistance or replacement options. Payers are increasingly asking for additional and highly specific evidence in the context of off-label requests, including biomarker data.

Handling Denials

Establishing a comprehensive denials and appeals process supported by meticulous documentation is a critical step for handling denials. Dr. Hudson-DiSalle noted that in some Medicare cases, requesting a redetermination is possible if the literature supports use of an investigational or off-label agent, since most fiscal intermediaries allow for coverage in the local coverage determination (LCD). Monitoring denial trends over time is another important step. Repeated denials might indicate the need for payer, billing, or provider education. Developing a "reconsideration packet" as a resource to challenge outdated payer policies can also be helpful. Ultimately, the oncology pharmacy team can strengthen care coordination in IO by being prepared, armed with data to support authorization and appeal denials, and by creating an audit trail that documents all clinical evidence, payer interactions, and appeals. ■

The content for this editorial is developed from the Evolving Role of the Oncology Pharmacy: Multidisciplinary Perspectives Pre-Conference at the ACCC 35th National Oncology Conference, October 17, 2018, in Phoenix, AZ.

The **Association of Community Cancer Centers (ACCC)** is the leading education and advocacy organization for the multidisciplinary cancer team. ACCC is a powerful network of 25,000 cancer care professionals from 2,100 hospitals and practices nationwide. ACCC is recognized as the premier provider of resources for the entire oncology care team. For more information, visit acc-cancer.org or call 301.984.9496. Follow us on Facebook, Twitter, and LinkedIn, and read our blog, ACCCBuzz.

The **ACCC Oncology Pharmacy Education Network** advocates on behalf of hematology-oncology pharmacists as vital members of the cancer care team, and is committed to developing educational resources and multidisciplinary connections that advance the field and elevate oncology pharmacy professionals to top-of-license practice.



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