

# ICLIO Webinar: Specialty Pharmacy — Managing Immunotherapy Access, Costs and Patient Expectations

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# Objectives

- Understand the role of specialty pharmacy in immuno-oncology through “real-world” examples:
  - Access, costs, and reimbursement
  - Pathways and formulary management
  - Managing patient expectations
  - Additional considerations and challenges

# Specialty Pharmacy

*Specialty Pharmacy refers to the distribution and handling of specialty drugs and biologics*

Specialty pharma includes drugs that have:

High Complexity

- Generally non-oral administered drugs/biologics that are injectable and that treat complex medical conditions

High Touch

- Drugs/Biologics that require specific types of distribution, special storage & handling, administration, and patient management; can require special clinical training

High Cost

- Drugs/Biologics that fall under specialty pharma can be very expensive – upwards of >\$400K per year; generally reimbursed through Medicare Part B, although can be covered under the Pharmacy Benefit

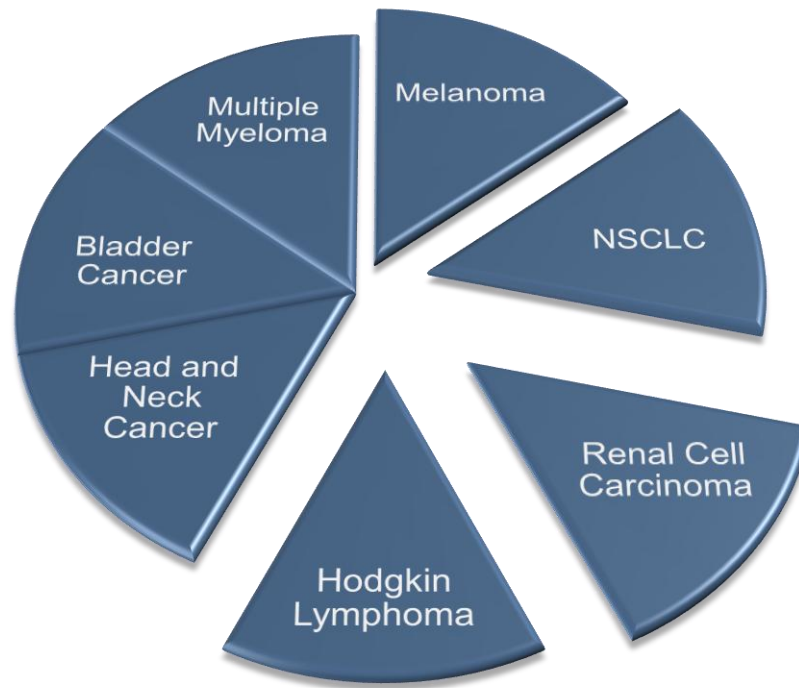
# Examples of Immuno-oncology therapies that fall under specialty pharmacy

Ipilimumab	Nivolumab	Pembrolizumab	Talimogene laherparepvec	Sipuleucel-t	Atezolizumab*
<ul style="list-style-type: none"><li>•Unresectable or metastatic melanoma</li><li>•Adjuvant treatment of melanoma</li></ul>	<ul style="list-style-type: none"><li>•Unresectable or metastatic melanoma</li><li>•Metastatic Non-Small Cell Lung Cancer</li><li>•Renal Cell Carcinoma</li><li>•Hodgkin's lymphoma*</li></ul>	<ul style="list-style-type: none"><li>•Unresectable or metastatic melanoma</li><li>•Metastatic Non-Small Cell Lung Cancer</li></ul>	<ul style="list-style-type: none"><li>•Unresectable cutaneous, subcutaneous, and nodal lesions in melanoma recurrent after initial surgery</li></ul>	<ul style="list-style-type: none"><li>•Metastatic castrate-resistant (hormone-refractory) prostate cancer.</li></ul>	<ul style="list-style-type: none"><li>•Treat bladder cancer, called urothelial carcinoma</li><li>•Targets the PD-1/PD-L1 pathway</li><li>•First product in its class (PD-1/PD-L1 inhibitors) approved to treat this type of cancer</li></ul>

***Five to six additional indications are expected for immunotherapies within the next year or two***

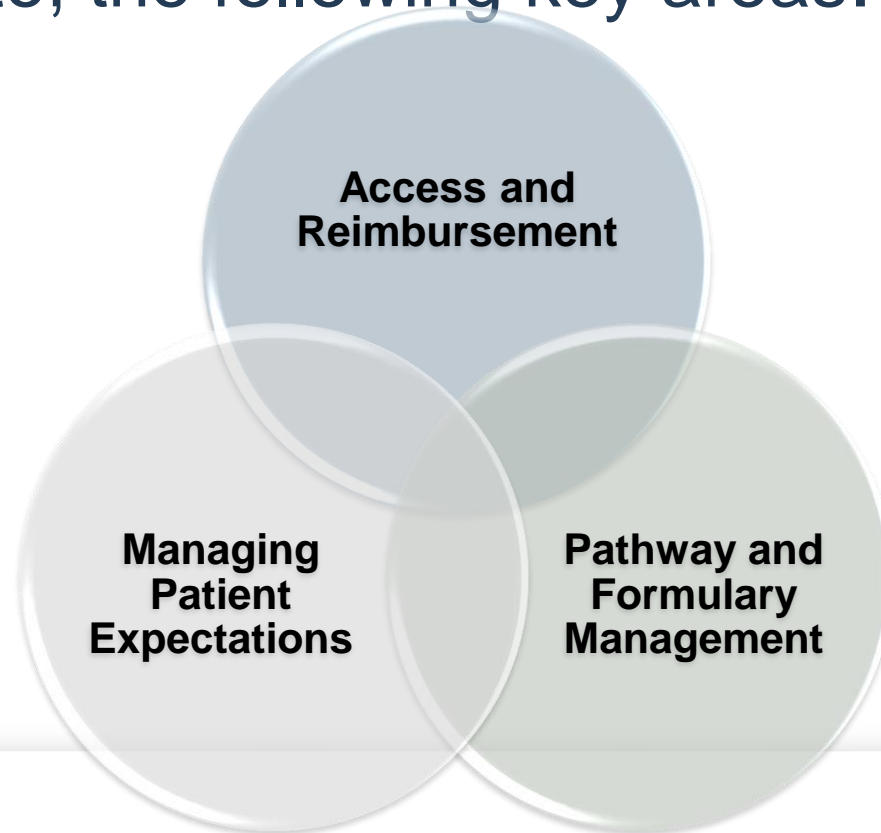
*\*Updated 5.19.16*

# Potential Scope of Indications with Immuno-oncology



# Specialty Pharmacy in Immuno-Oncology

- Roles in immuno-oncology include, but are not limited to, the following key areas:



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# Specialty Pharmacy in Immuno-Oncology

## Access and Reimbursement

Specialty pharmacy and oncology pharmacists manage inventory, distribution, and dispensing of immunotherapies

Immunotherapies such as nivolumab and pembrolizumab can be cost-prohibitive for patients; this is especially true for combination immunotherapies (e.g. nivolumab + ipilimumab for melanoma)

- Oncology pharmacists work with financial staff and the finance department to provide access to immunotherapies (e.g. patient assistance programs, tiered formularies, etc.)

Oncology pharmacists ensure proper on-label use; with regards to off-label use, oncology pharmacists will work with both public (e.g. Medicare) or private (United, Aetna, Humana, etc.) payers for approval and reimbursement

# Managing Immunotherapy in Clinics

- Oncology Clinical Pharmacists work with physicians and providers to address on-label and off-label access
  - Off-label therapies are interpreted with the physician teams to address current data
    - Data in the chemotherapy order is documented with off-label references and guidelines recommendations
  - Finance and our financial counselors are immediately contacted
  - Pharmacy is made aware off the process for inventory control management



# Specialty Pharmacy in Immuno-Oncology

## Access and Reimbursement

*Other considerations*

- 340B Drug Pricing Program
  - Discounts on drugs and biologics from manufacturers given to hospitals and other covered entities (on average, discount is ~22.5% of ASP)
  - To be eligible for the 340B program, hospital must have a minimum disproportionate share percentage based on the share of a hospital's inpatients who are Medicaid or low-income Medicare patients  
*(source: Report to the Congress, Overview of the 340B Drug Pricing Program, May 2015)*
  - Medicare and other insurers will reimburse the same amount for Part B drugs to 340B participating and non-340B hospitals
- Contracting
  - Hospitals and payers will negotiate contracts to:
    - Manage costs
      - Managed care provides a significant percentage of revenue for a hospital; ensures patient access to treatment and services
      - Provides access to managed care products and pilot projects that could increase revenue for the hospital (e.g. risk-sharing models, value-based benefit designs, etc.)
    - Manage usage
      - Formulary management
      - Preferred drugs, prior authorizations, QLs, etc.
    - Have a more efficient distribution channel

# Specialty Pharmacy in Immuno-Oncology

## Pathway and Formulary Management

- Oncology Pharmacists are actively involved in deciding which drugs and biologics are placed into hospital formularies; pharmacists are integral members of institutional Pharmacy and Therapeutics (P&T) Committees

- In addition to formularies, many hospitals or institutions utilize Pathways which are either developed within the institution or are provided by third part organizations

Pathways are decision support tools that use established oncology clinical guidelines (e.g. NCCN Guidelines) and literature to determine the most effective, least toxic, and least costly therapies for a particular tumor type (*source: <https://www.advisory.com/research/oncology-roundtable/oncology-rounds/2013/11/oncology-clinical-pathways-faq>*)

***Oncology pharmacists are integral in deciding which immunotherapies are utilized in an institution***

# Specialty Pharmacy in Immuno-Oncology

## Pathway and Formulary Management

- Examples of outside organizations that provide Pathways include:
  - VIA Oncology
  - eviti
  - McKesson/US Oncology Value Pathways powered by NCCN
  - New Century Health

***With an emphasis on value-based care, Pathway companies are partnering with payers, adding a layer of complexity for hospitals and oncology pharmacists regarding access and reimbursement***

# Integration of Therapies for P&T Consideration

- The University of Arizona Cancer Center (UACC)
  - Formulary decision-making
    - Inpatient/Outpatient
      - Integration of the Oncology Service Line
      - Based on Utilization and Indications
      - Based on Electronic Medical Record Indication
  - Extent of which pathways are utilized in UACC
    - Institutional Based Formulary
      - Pathway are Based on Payor Pathways for Treatment
      - Utilize pathways from third party?
    - Case study – how insurance companies are starting to utilize pathways for preferred therapies and how that may affect utilization within ACC – getting the right therapy to patients

# Specialty Pharmacy in Immuno-Oncology

**Managing  
Patient  
Expectations**

***Patient Financial  
Resources***

As mentioned previously, immunotherapies are expensive and can be a financial burden to patients; oncology pharmacists assist patients by providing resources and programs that can help patients pay for these therapies; oncology pharmacists can:

- Provide education regarding finance and other resources
- Manage and enroll patients in patient assistance programs (PAP) or assist in finding alternative financial or advocacy based programs

# Specialty Pharmacy in Immuno-Oncology

**Managing  
Patient  
Expectations**

***Medication Therapy  
Management***

- Immunotherapy stimulates an innate response against tumor cells; as a result, patients can experience immune-related Adverse Events (irAEs)
  - Oncology pharmacists will work with the multidisciplinary team (i.e. physicians, nurses, advanced practitioners) to mitigate and manage irAEs through supportive care, lab testing, etc.
- As part of the multidisciplinary care team, oncology pharmacists play an integral role in patient adherence
  - Form a relationship with the patient
  - Educate the patient on possible irAEs
  - Supply necessary tools and resources to keep patients on their immunotherapy

# Incorporation of PAP into patient workflow

- Patient Example
  - Patient is evaluated for off-label therapy based on current indications and clinical data
    - Content is entered into our EMR
      - Supporting Data, Reason for Treatment and Recommendation Guidelines
    - Clinical Oncology Pharmacists discusses the content with Finance
      - Financial Counselors then address content for PAP with the patient
  - Finance team then works on the prior authorization for the patient
    - Address pathways (if applicable to disease team management)
    - Address Insurance content for approval
  - Financial Counselors
    - Address Co-pay Assistance for patients
    - Work on Drug Replacement/Free Drug Therapy for patients
    - Will address approval for start date
  - Pharmacy
    - Made aware of free drug replacement
    - Charge codes are changed for administration

# Electronic Health Record (EHR) and Electronic Medical Record (EMR)

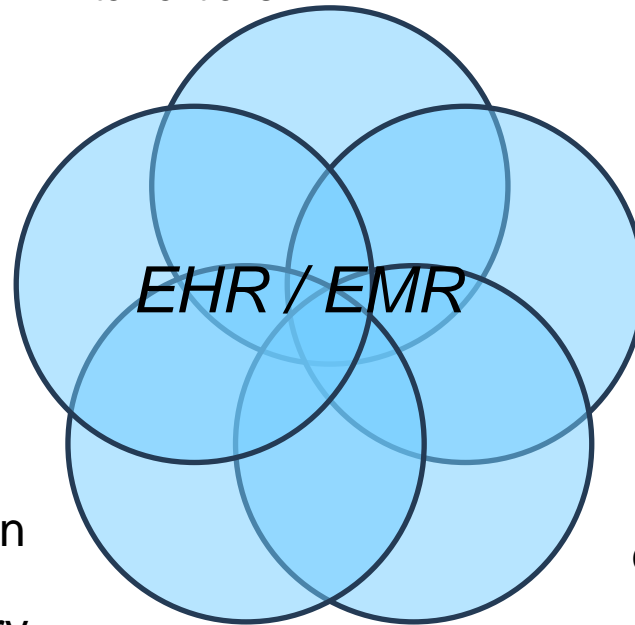
Document and track patient care electronically

- Diagnosis, stage, tumor pathology, progression, adverse events/toxicities, lab results, interventions

Appropriate billing and codes

Health history

- Medical history, current medications



Communication between the multidisciplinary cancer care team

Incorporation of evidence-based guidelines, pathways, and formulary



# Electronic Health Record (EHR) and Electronic Medical Record (EMR)

## Advantages / Benefits

- Data
  - Track sequencing of therapies, outcomes, cost of delivered care
- Consistencies through integrated guidelines / pathways / formulary
- Improved efficiencies and cost-savings
- Communication between departments and with patients
  - Information can be received or given via other electronic devices (e.g. personal electronics)
- Allows for participation in national programs, value-based programs, pilot programs

## Disadvantages / Challenges

- Integration between departments, between other hospitals using different systems (e.g. patients information between different networks)
- Training of all members of the multidisciplinary team
- Electronic – need reliable back-up storage
- Incorrect data (e.g. incorrect dosing information, incorrect product information) can propagate throughout the entire EHR system

*Examples of EHR systems include Epic, Cerner, Sunrise iKnowMed, Elekta, and Mosaiq*

# Integration of EMR Workflow with Oncology

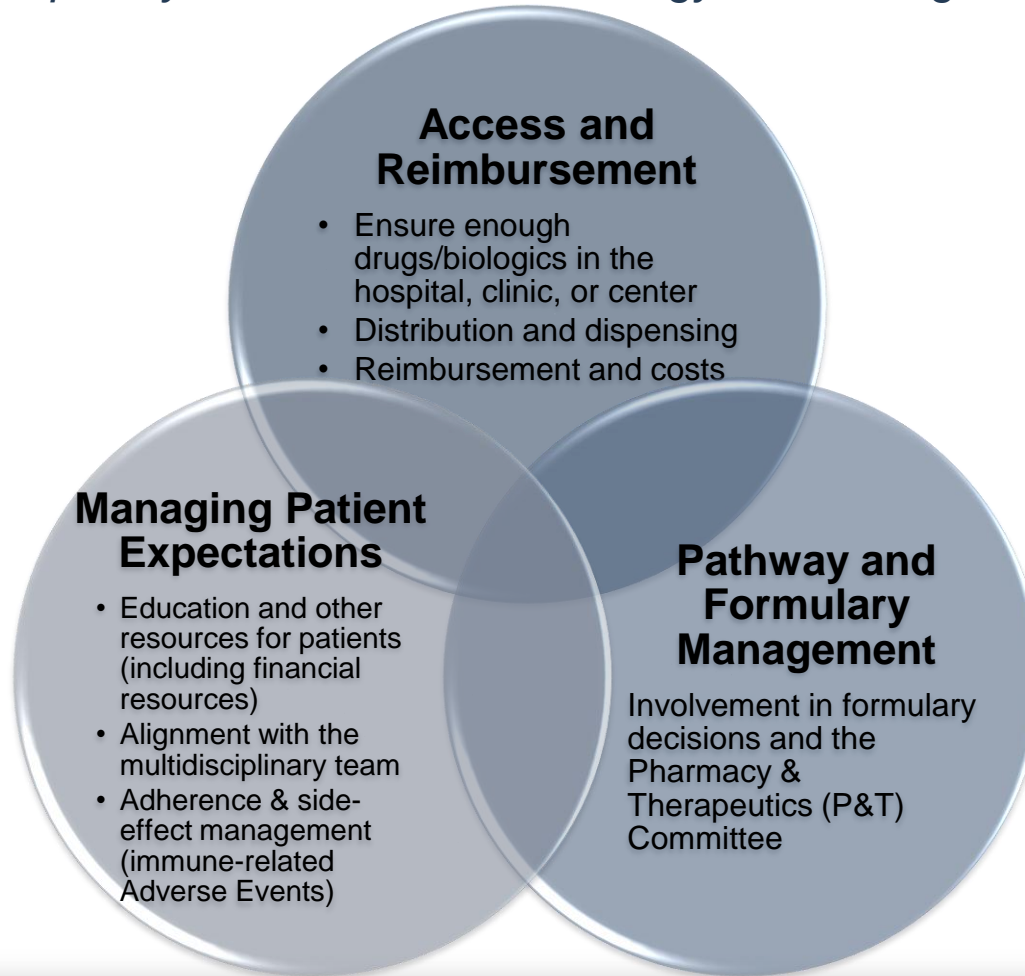
- The University of Arizona Cancer Center
  - Epic
  - Beacon
    - Consolidated our pathways for supportive care measures
    - Maximized Reporting Structures for Chemotherapy
      - Current Disease State Treatments
      - Dosing Changes
      - Off-label based treatments
    - Documentation of Drug Waste
  - Improved Care for outcome measurements in Cancer Care
    - Transition of Care
    - Oral Chemotherapy
    - Financial Approvals/Patient Assistance Notification
      - Drug Replacement Programs
    - Patient Treatment Workflow

# Specialty Pharmacy – Additional Considerations

- Additional considerations include:
  - Managing drug waste
    - This is a concern in specialty pharma, especially because of the high cost of immunotherapies
  - Distribution
    - “White bagging” and “Brown bagging”
      - » White bagging can result in loss of storage space for hospitals who are forced to store drugs/biologics not purchased by the hospital; clinicians are not reimbursed for administration of drugs/biologics from White bagging; lost revenue as a result of no buy-and-bill model
      - » Brown bagging can result in compromised drug or biologic integrity since it is the patient’s responsibility to store and transport the drug/biologic to the hospital, center, or clinic for administration
  - Preventing duplicative efforts within the specialty pharmacy multidisciplinary team with regards to patient management

# Summary

*Specialty pharmacy / oncology pharmacists play an essential role as part of a multidisciplinary team in immuno-oncology that manages the following:*



*In addition, tools such as EHR and EMR systems are integral components of specialty pharmacy, improving total patient care within hospitals/clinics/centers*

# Questions?



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