ICLIO Webinar: Communicating with Payers 101

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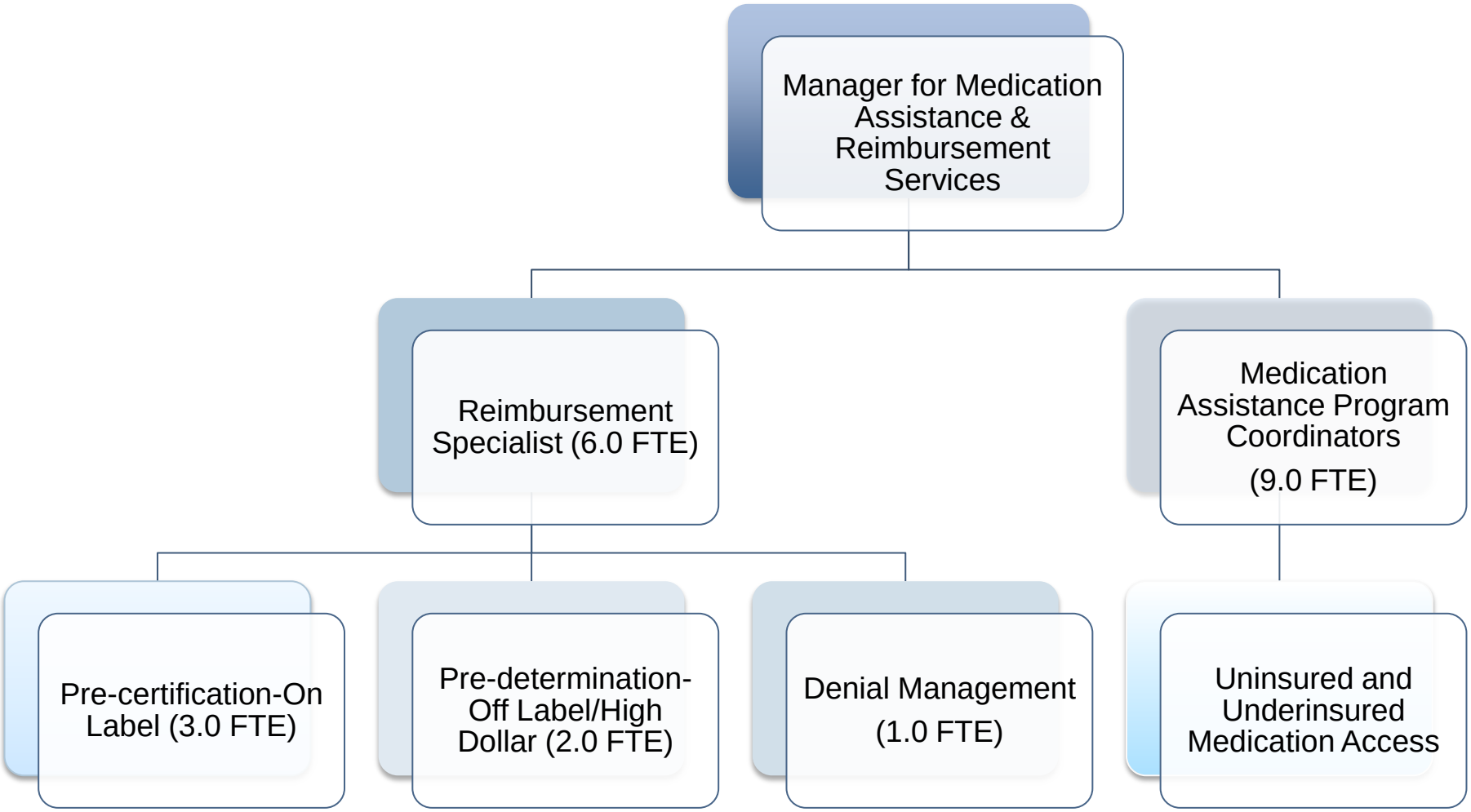
INSTITUTE FOR CLINICAL IMMUNO-ONCOLOGY
AN INSTITUTE OF ACCC
Association of Community Cancer Centers
accc-iclio.org

Off-Label Disclosure

- I do intend to discuss off-label uses of products during this activity

Overview

- Discuss approved and unapproved uses of immuno-oncology (I-O) agents
- Review current experience with payer reimbursement of I-O agents
- Explain the importance of understanding payer policies/requirements for I-O agents and proactively interacting with payers
- Describe resources that are necessary to avoid denials and ensure payment for I-O agents


Manager for Medication Assistance & Reimbursement Services
Reimbursement Specialist (6.0 FTE)
Medication Assistance Program Coordinators (9.0 FTE)
Pre-certification-On Label (3.0 FTE)
Pre-determination-Off Label/High Dollar (2.0 FTE)
Denial Management (1.0 FTE)
Uninsured and Underinsured Medication Access

Current I-O Agents

- Pembrolizumab (Keytruda®) - Merck
- Nivolumab (Opdivo®) - Bristol-Myers Squibb
- Atezolizumab (Tecentriq®) -Genentech

FDA Approved Uses

- Pembrolizumab (Keytruda®) - *Merck*
  - Treatment of patients with unresectable or metastatic melanoma
  - Treatment of patients with metastatic NSCLC whose tumors express PD-L1

FDA Approved Uses

- Nivolumab (Opdivo®)-*Bristol-Myers Squibb*
  - Treatment for previously treated metastatic non-small cell lung cancer
  - Treatment for patients with metastatic melanoma across BRAF status
    - As a single agent
    - In combination with ipilimumab
  - Treatment for advanced renal cell carcinoma in patients who have received prior anti-angiogenic therapy
  - Treatment for adults with relapsed or progressed cHL after auto-HSCT and post-transplantation brentuximab vedotin

FDA Approved Uses

- Atezolizumab (Tecentriq®)-*Genentech*
  - Treatment for locally advanced or metastatic urothelial carcinoma in patients who were previously treated with platinum-containing chemotherapy

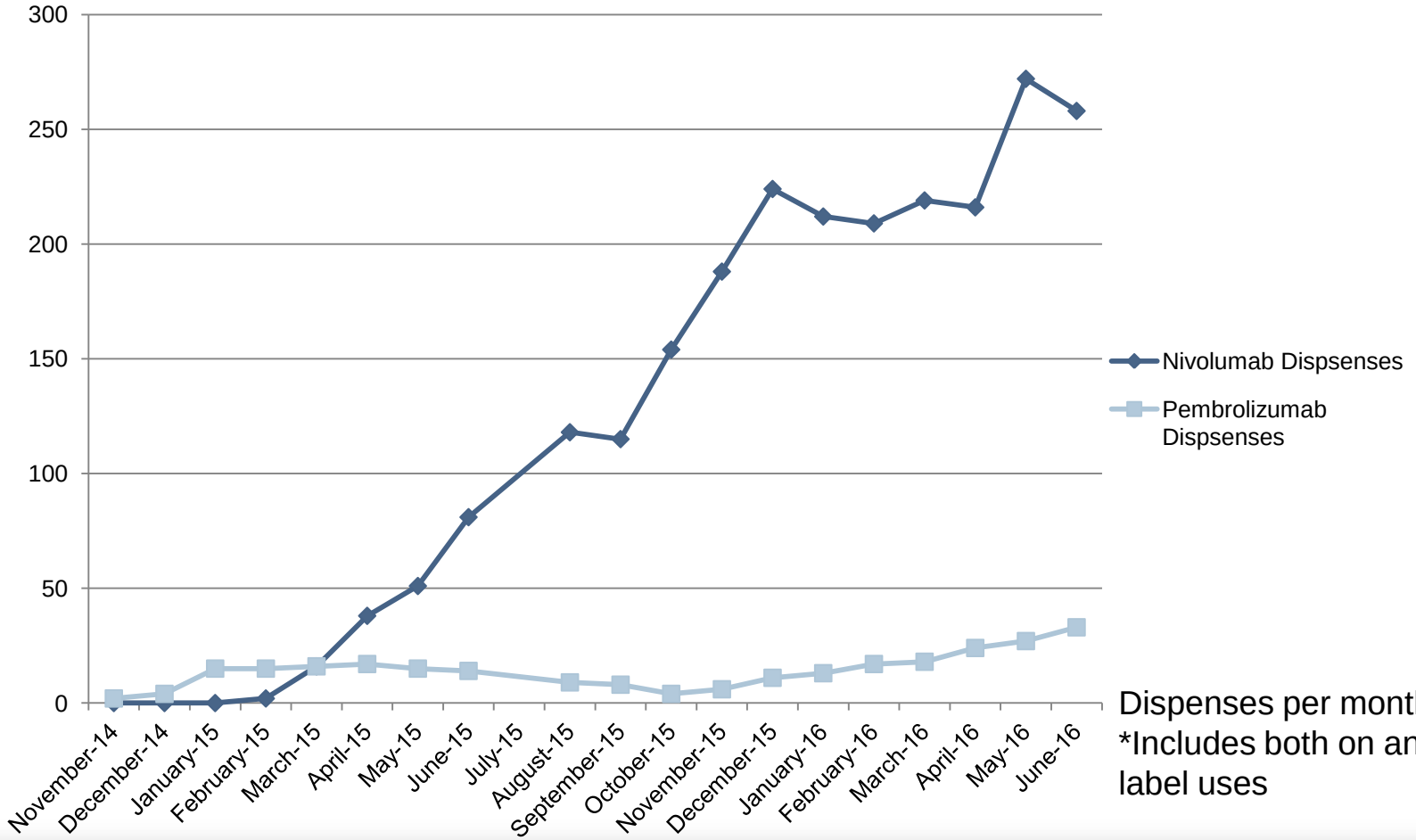
Sample of Unapproved I-O Uses

- 1st line metastatic adenosquamous non-small cell lung cancer (nivolumab)
- Squamous cell carcinoma of head and neck (nivolumab)
- Mesothelioma (nivolumab)
- Glioblastoma (nivolumab)
- Neuroendocrine carcinoma (nivolumab)
- Recurrent squamous cell cancer of vulva (nivolumab)
- Esophageal cancer (nivolumab)
- Metastatic breast cancer (nivolumab)
- Inflammatory myofibroblastic tumor (nivolumab)
- Diffuse large B-cell lymphoma (pembrolizumab)

Increased Patient Awareness Results in Increased Demand

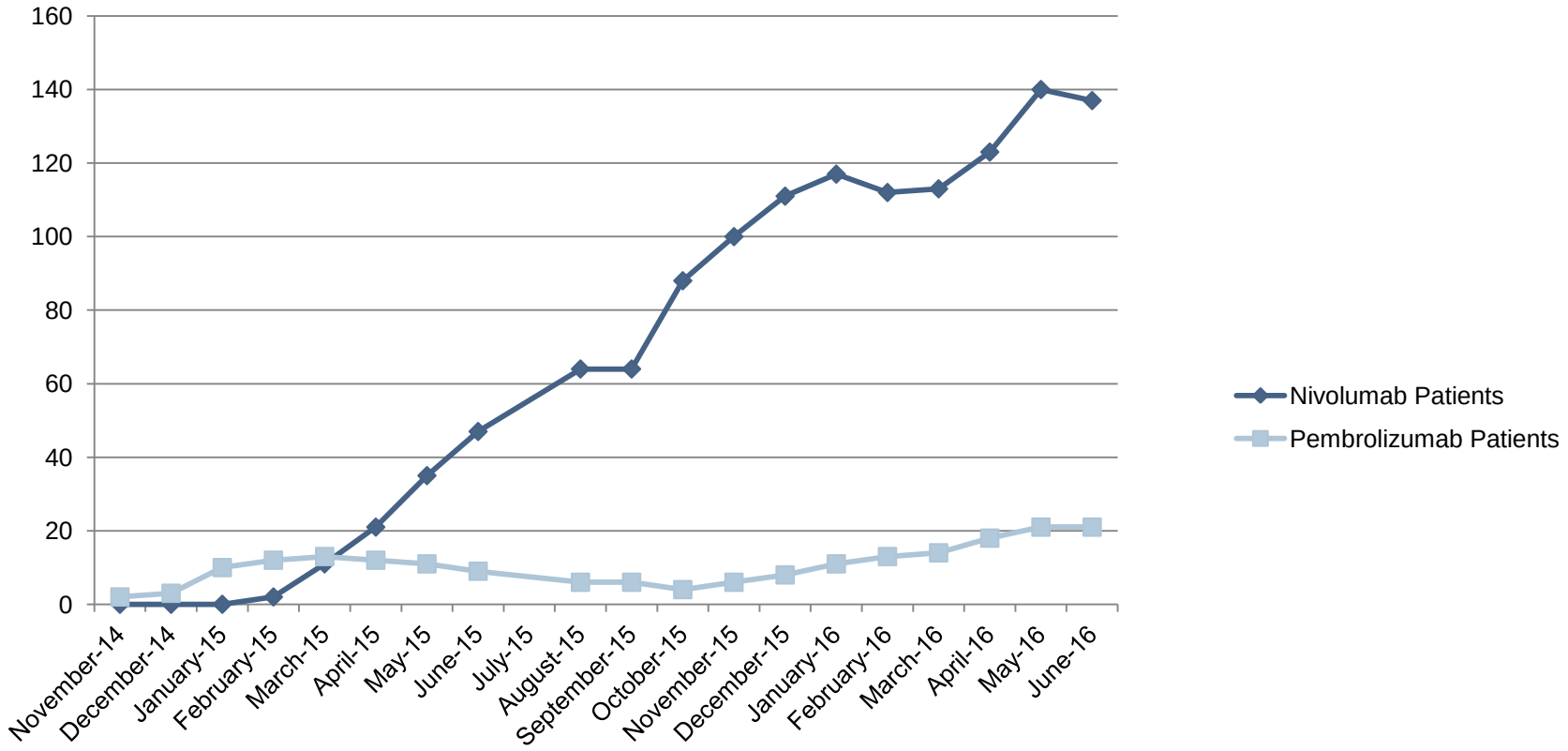
- Marketing campaigns through television advertisements
  - Drive patients to inquire about specific therapies
  - Messaging brings hope and optimism to diseases where previous options were limited
  - President Jimmy Carter's success provides an inspiring patient testimonial
- Demand for 1st line therapy from patient and providers is increasing

Snapshot of I-O Dispenses at the James



Dispenses per month
*Includes both on and off label uses

Snapshot of I-O Patients at the James



Unique patients per month
*Includes both on and off label uses

Payer Response to I-O Agents

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Medicare Response

- Most Medicare Administrative Contractors (MAC) have at least one I-O agent LCD
- Some MAC have separate LCD for all three agents
  - CGS published atezolizumab LCD within the first six weeks of release of the agent
- No successful reimbursement outside the FDA label indications
- No National Coverage Determinations to date

Commercial Payer Response

- Clinical policy guidelines and pathways
  - Vendor Pathways examples: Well Point, New Century Health, AIM
  - Clinical policies examples: Anthem, Aetna, UHC, Cigna, Humana
- Often the clinical policies require medication eligibility restrictions beyond the label and additional criteria to be met in order to assure reimbursement
  - Example: Anthem clinical policy for nivolumab includes patient's current ECOG score 0-2 be met

Commercial Payer Response

- Use of maximum dosages for usage regardless of weight
  - Maximum allowable units per day and per date span for specialty drugs
- Use of National Drug Code (NDC) units verse CPT/Healthcare Common Procedure Coding System (HCPCS) units creates confusion and concern for underpayment
  - HCPCS units measure the strength of the drug administered
  - NDC units measure the quantity or volume of the drug administered
    - Monitor closely for errors in underpayment and errors

Commercial Payer Response

- Disproportionate approvals of total doses quantity over a period of time
  - Example: Authorization for 90mg pembrolizumab for 6 infusions but date range is for nine months- *Make sure that the dates and authorizations match*
- Retrospective denials, particularly for off-label uses, even when there was a pre-determination in acceptance of the use

Commercial Payer Response

- Billing for waste with immuno-oncology agents
  - Proper usage of the JW modifier
    - JW modifier will indicate the amount of waste volume represented
    - I-O agents that are single-use vials or single-use package for unused portion are eligible
    - Multi-dose vials are not eligible
  - Not all payers will pay for waste
  - Some payers do not allow rounding of doses and do not pay for waste (a lose/lose situation for providers)
  - Proper documentation necessary in the medical record for discarded waste
    - Mandated wastage rationale for any JW lines on Medicare claims on January 1, 2017

The James Response to Payer Requirements for I-O agents and other High Dollar Medications

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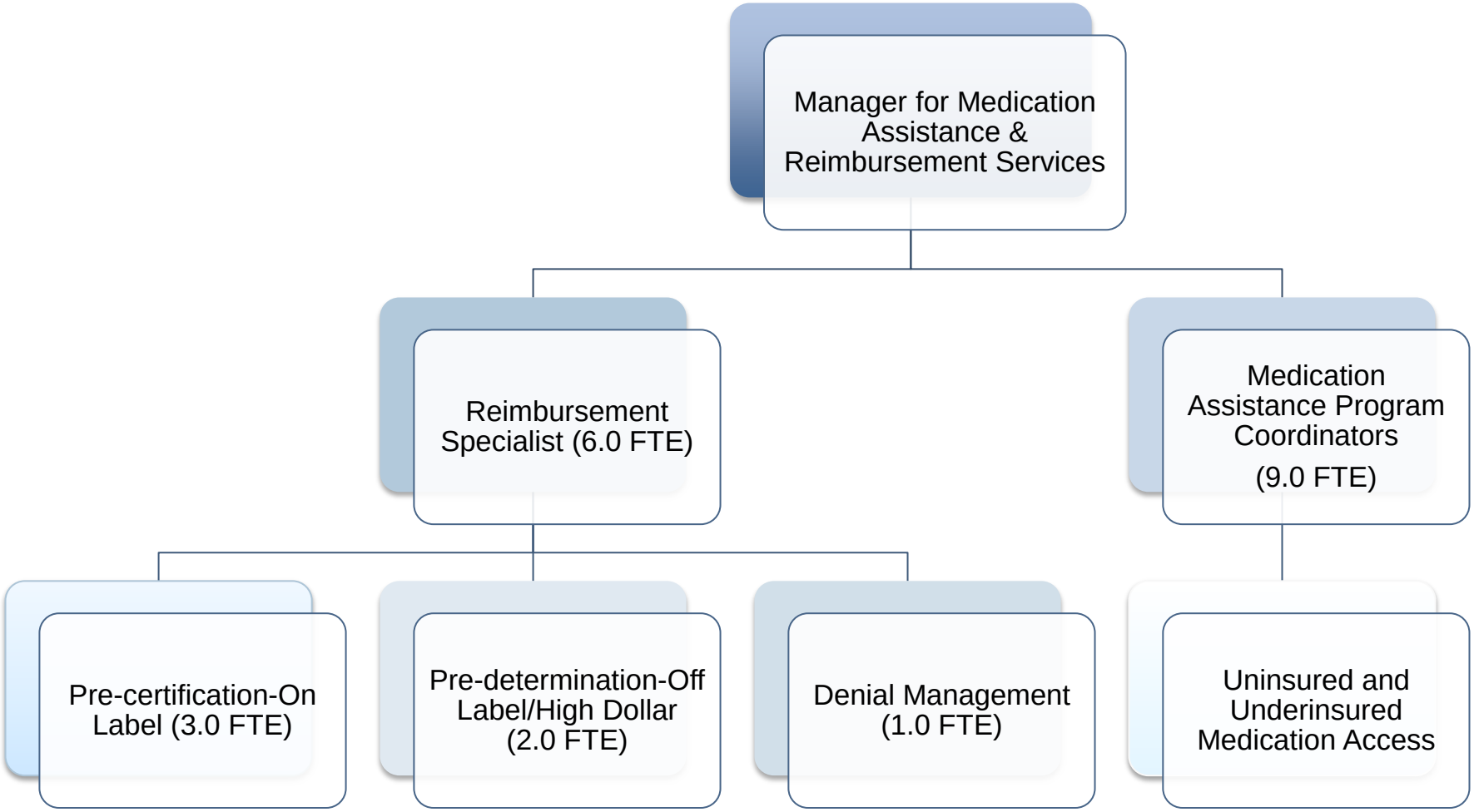
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Reimbursement Specialist Role

- Qualifications:
  - Clinical background, ideally with experience in oncology
  - Fundamental understanding of payer terminology and requirements
- Important qualities:
  - Self-sufficient and ability to multitask
  - Independent and motivated
  - Strong prioritization and organizational skills

Reimbursement Specialist Responsibilities

- Perform all types of approvals (precertification, predeterminations, high dollar approvals)
- Gather all clinical and supporting evidence and submit to payers
- Communicate status requests to stakeholders
- Educate clinical staff on policies and requirements for authorization
- Display a strong understanding of the disease implications, use of various treatment modalities, and expected outcomes

Reimbursement Specialist Responsibilities

- Follow-up on rejected and denied claims using evidence based support and other documentation as needed
- Identify trends in denials and provide education to clinical staff and managed care payers to reduce these denials
- Work with medical information management to ensure proper ICD-10 and CPT coding are performed on patient claim

Precertification Essentials

- Develop a form of notification to identify when precert is needed
  - Work queue or other trigger to indicate that a patient is scheduled to receive a medication on the precert list
    - Our trigger is not payer specific so the medication is flagged regardless of specific payer requirement
- Determine medication eligibility
  - Requires review of payer specific documents
    - In the absence of a document or clinical guideline, institutional policy determines if precert is warranted based on cost and experience with other payers
    - We often request a complimentary precert for high dollar medications and/or because policies change frequently

Precertification Essentials

- Educate staff on precert guidelines/requirements of major payers
  - Evidence based guidelines (e.g. NCCN)
  - CMS approved compendia
  - Clinical policies from insurance providers (e.g. Anthem)
- Ensure authorization requests are comprehensive and legible
- Build relationship with case managers at third party administrators (TPAs) used by major payers

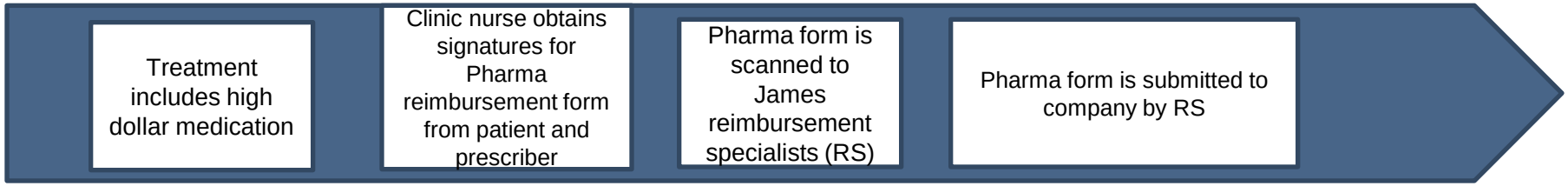
Precertification Essentials

- Follow-up with TPA or payer for authorization
  - National Committee for Quality Assurance states non-urgent precertification requests must be answered within 15 calendar days of receipt of the request
- Obtain the authorization in electronic format for use at a later date in the event of a denial

High Dollar Process

- We use the support programs whether on or off-label for all medications (in addition to our own precert or pre-D process)
- Patients are screened at time of scheduling
  - Work queues, clinic nurse and pharmacy involvement
- Developed reports to assist in the screening
  - Cycle One/Day One reports
- Claims are followed to ensure reimbursement

High Dollar Process



On Label Request

Full benefits investigation performed by Pharma services and referral to copay and PMAP resources provided if necessary

Patient coverage verified by RS

Denied

Request submitted to payer for approval

Approve

RS communicates with pharmacist and team once authorization is approved

Patient scheduled for therapy

Off Label Request

Refer to Off label policy and procedure

Follow account to ensure payment and application of copay assistance

Medication Assistance Program Coordinator (MAPC) speaks with patient about benefits and need for copay or PMAP assistance

MAPC assists with copay or PMAP assistance

Coordinate with business office to submit copay grants

Pre-determination Essentials

- Effective, accessible and traceable form of communication is essential
  - To document initial request for off-label use for transmission to reimbursement specialist
  - For all parties to be able to be able to determine status of the request at any point in time
- We use a home grown database located on the Pharmacy Intranet and have data back to 2003 on off-label medication use

Pre-determination Essentials

- Verify medical insurance
- Obtain copies of pertinent information from patient medical record (treatment plan, diagnostic studies, etc.)
- Retrieve supporting literature (if not already provided by team)
- Verify compendia and NCD/LCD support
- Identify appropriate ICD-10 code(s) and HCPCS code(s) for medications
- Draft letter of medical necessity
- Fax letter and supporting evidence to payer
- Confirm payer has received information
- Continue to follow-up until approval/denial received
- Request approval number and individual name

Pre-determination Essentials

- Communicating with payers
  - Need to be clear you are requesting approval for an OFF-LABEL use for cancer treatment
  - Need to state that you are calling about an intravenous infusion from an outpatient oncology clinic versus from an outpatient pharmacy (i.e., medical benefit, not pharmacy)
  - Payers have different requirements for approval (i.e. literature support)
  - Different payer = different departments to contact
    - Medical Review, Case Management, Predetermination, etc.
  - Keep copies of all authorizations granted

Getting Paid for I-O Agents and Other High Dollar Medications

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Common Reasons for Denials

- Lack of pre-certification or authorization
- Medical necessity
- Experimental and investigational
- Requires additional information
- Non-covered service/medication on the plan benefit
- Out of network provider
- Timely filing of claims
- Multiple diagnoses coding for disease states and metastases- payer does not apply correct codes to medications
- Error in number of units billed to payer

Handling of Denials

- Work with Finance to develop a method for routing denials to appropriate personnel
  - Leverage IT to create work queue and notification process
- Consider appropriateness of resources
  - Workload (average number of denials/appeals)
  - Strict appeal timelines of many payers
- Consider training/experience of personnel
  - Ideally a nurse or pharmacist with oncology experience
  - Ability to learn and understand financial systems and processes
  - Done by Reimbursement Specialists at The James

Handling of Denials

- Review payer specific policy, LCD, NCD
- Determine if precertification or prior authorization was completed
  - Approval number and representative name listed
  - Precertification or prior authorization does not guarantee payment
- Review documentation
  - Reimbursement is linked to the quality of the bill
  - Coders obtain information from medical record but sometimes required information is missing

Handling of Denials

- Request medical peer to peer interaction
  - Offer additional information and rationale to discuss with clinical reviewers who made initial adverse determination
- Monitor for trends
  - Increased denials for repetitive reasons may require payer, billing or provider education
- Hold payer accountable
  - Regardless of the size of the organization
    - Example: Payer not recognizing authorization because it came from a third party administrator and denying claims for reason of “lack of pre-certification”

Handling of Denials

- Challenge outdated payer policies
  - Develop reconsideration packet (for both commercial payer and Medicare) with evidence to support addition of covered diagnoses and/or regimens excluded from payer policies

New Agent Challenges

- Payer policies lag behind FDA label changes and new medication approvals
  - ALWAYS ask for permission and ensure that any new high dollar medication will be paid for in advance of administration
- New payer authorization requirements often are not effectively communicated
  - Retro-authorization becoming obsolete
- Resource and time intensive to perform all steps in process

New Agent Challenges

- Unclassified drugs or biologicals
  - C9399- hospital outpatient setting
  - J9999- physician and clinic setting
  - Required: NDC number, quantity of drug administered and date of administration
- Temporary codes
  - Once the unassigned code period has passed, CMS assigns a temporary code until a permanent code is assigned by CMS
  - Some payers do not recognize the temporary code and it may cause denials

Tips for Successfully Working With Payers

- Designate *dedicated* staff to perform precert, pre-D, and handle denials
  - Assists with development of relationships with payer clinical teams and medical review personnel
- Review clinical policy bulletins/newsletters (monthly/quarterly)
- Regularly review on-line payer policies
  - Detail medications which the payer considers medically necessary verses experimental or unproven and requirements for payment

Tips for Successfully Working With Payers

- Gain a seat at the table
  - Attend in person managed care quarterly meetings to hear updates, elevate issues, and build relationships
- Work to remove obstacles between new research and clinical practice and reimbursement
  - Provide clinical evidence to alter clinical policies
  - Updates to payer clinical policies occur on an annual or as needed basis- very limited opportunities to change
  - Develop relationships with the pharmaceutical account reimbursement representative to leverage ability to make payer impact and change on practice

Future Considerations

- Payer ability to keep up with accelerating evidence based new indications (e.g., new lines of therapy, new tumor types)
- Increasing utilization of anti-PD1s in combination with a host of agents (e.g., chemo, targeted, immunotherapeutic)
- Financial implications of agents becoming first line

Questions?

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Register for the ICLIO National Conference September 30, 2016 Philadelphia

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Presentation slides and archived recording will be available at accc-iclio.org

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