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Pharmacy Operations and Issues in Academic and Community Settings

Niesha Griffith, MS, RPh, FASHP

Vice President, Cancer Services

WVU Medicine

West Virginia University Health System

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ICLIO INSTITUTE FOR CLINICAL IMMUNO-ONCOLOGY

AN INSTITUTE OF ACCC Association of Community Cancer Centers

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Overview

- Current Coverage
- Reimbursement Polices
- I-O Payment Challenges
- Reimbursement and Patient Support Recommendations

Off-Label Use Disclosures

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

Current I-O Agents

- Keytruda® (pembrolizumab)- Merck
- Opdivo® (nivolumab)- Bristol-Myers Squibb
- Tecentriq® (atezolizumab)-Genentech

FDA Approved Indications for Pembrolizumab

- Unresectable or metastatic melanoma
- Metastatic non-small cell lung cancer
  - patients with metastatic NSCLC whose tumors express PD-L1 as determined by an FDA-approved test and who have disease progression on or after platinum-containing chemotherapy
    - patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving pembrolizumab
- Patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy

FDA Approved Indications for Nivolumab

- Unresectable or metastatic melanoma
  - BRAF V600 wild-type as a single agent
  - BRAF V600 mutation positive as a single agent (approved under accelerated approval based on PFS)
  - in combination with ipilimumab (approved under accelerated approval based on PFS)
- Metastatic non-small cell lung cancer
  - patients with progression on or after platinum-based chemotherapy; patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to nivolumab

FDA Approved Indications for Nivolumab

- Advanced renal cell carcinoma in patients who have received prior anti-angiogenic therapy
- Classical Hodgkin lymphoma that has relapsed or progressed after autologous (HSCT) and post-transplantation brentuximab vedotin

FDA Approved Indication for Atezolizumab

- 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)
- 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)

Reimbursement Policies

Medicare

- 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 Payers

- 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 Payers

- 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 Payers

- 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 Payers

- 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 or only pay for part
  - Some payers do not allowing 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

I-O Payment Challenges

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New Agent Challenges

- Requests for off-label use immediately following FDA approval
- Payer policies lag behind FDA label changes and new medication approvals
  - Payers initially not prepared to answer coverage questions and render decisions
  - 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

- Support programs are different
  - Testing requirement
  - Off-label support (initially)
- Resource intense and time intensive to perform all the steps in the process
  - Clinical team (physicians, pharmacists, APPs)
  - Reimbursement staff
- Out of pocket payments

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

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

Reimbursement and Patient Support Recommendations

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Reimbursement

- Require precertification for all on-label uses and enroll all patients in manufacturer-sponsored program for benefits investigation/copay support
- Designate *dedicated* staff to perform precert, pre-D, and handle denials
  - Assists with development of relationships with payer clinical teams and medical review personnel
- Develop an off-label policy for IO therapies
  - Require predetermination for all off-label requests
  - Enroll all patients in manufacturer-sponsored program for benefits investigation, appeals, and potential medication replacement
  - Ensure patients are made aware of risks and benefits, including financial
  - Require patients to sign an Advanced Beneficiary Notice or Notice of Non-Coverage

Reimbursement

- Ensure process is in place for appropriate management/billing until J-Code is assigned
- 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

Reimbursement

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

Patient Support

- Identify a point person to focus on I-O agents and understand the nuances of the various manufacturer programs, co-pay foundations, and patient assistance programs to optimize reimbursement and patient support
- Ensure your practice has sufficient Patient Advocate support
  - Most practices have found that Financial Counselors/Medication Assistance Coordinators pay for themselves many times over; if you are not sure if you have enough, it’s a good time to conduct an analysis

Patient Support

- Be prepared for patients who may be willing to pay for I-O therapies out of pocket
  - Patient advocates should be well versed in having that conversation with patients in addition to talking about their benefits and potential support program assistance

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)
- Potential for coverage policies to be biomarker driven (e.g., PDL1 overexpression)
- Financial implications of agents becoming first line

Questions?