Disclosures

• ARIAD Pharmaceuticals, Inc., Consulting Fees
• I will be discussing non-FDA approved treatments/indications during my presentation.
Medicare

• Most Medicare Administrative Contractors (MAC) have at least one I-O agent Local Coverage Determination (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 (NCD) to date
Commercial Payers

• Policies primarily based upon published scientific evidence

• 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
Commercial Payers

- Disproportionate approvals of total doses quantity for a specific 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*

- Always pursue authorization/pre-determination for IO’s, regardless of whether the therapy is on or off-label
  - Retrospective denials often occur, 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
Denials – common reasons

- 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
General Rules for Denials

• Discover the root cause of the denial
  ▪ Review payer specific policy, LCD, NCD
  ▪ Determine if pre-certification or prior authorization was completed
  ▪ Review documentation
    ▪ Reimbursement is linked to the quality of the bill
    ▪ Coders obtain information from medical record but sometimes required information is missing

• Look for denial trends with payers
  ▪ Drugs, diagnosis, charge threshold
Handling 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
Handling Denials

• Request medical peer to peer interaction
  • Offer additional information and rationale to discuss with clinical reviewers who made initial 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 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
Case Example:

• Request for Ipilimumab 3mg/kg and Nivolumab 1mg/kg every 3 weeks combination followed by Nivolumab 3mg/kg every 2 weeks for metastatic melanoma to the genital region & lymph node

• Diagnosis code: C43.72, C79.82, C77.4

• Insurance: Anthem

• Cost of therapy: $136,728

• Level of evidence:
  • NCCN level of evidence 2A
  • Anthem clinical policy
Case Example:

• Initial thoughts?
  ▪ Case meets NCCN and Anthem Clinical policy guidelines

• Concern for reimbursement?
  ▪ None

• What happened next...
  ▪ Denied for Experimental and Investigational usage
Case Example:

• Final outcome
  ▪ Submit an appeal that contained:
    ▪ Infusion orders and pharmacy records
    ▪ Nursing administration and performance status assessment
    ▪ Prescriber clinical records
    ▪ Authorization for treatment from AIM pharmacy specialty services
    ▪ Current lab and scan results

• Appeal successful and reimbursement granted
Case Example:

- Request for nivolumab 3mg/kg every 2 weeks for metastatic epithelioid sarcoma with metastatic disease to the lung, scalp, kidney and soft tissue
- Diagnosis code: C49.9, C78.02, C77.4
- Insurance: Aetna
- Cost of therapy: $75,064
- Level of evidence: Case studies
Case Example:

• Initial thoughts?
  ▪ Patient has failed multiple lines of therapy
  ▪ Aggressive disease
  ▪ Limited data

• Concern for reimbursement?
  ▪ High concern for denial

• What happened next…
  ▪ Complete pharmaceutical enrollment form
  ▪ Submit pre-determination
Case Example:

• Final Outcome:
  ▪ The pre-determination was submitted to Aetna
  ▪ Initially the case was denied
  ▪ Peer to peer appeal was arranged
  ▪ Denial was over turned
  ▪ Claims were submitted and reimbursed after appeal for experimental and investigational denial after bill was received.

• Appeal successful and reimbursement granted
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?