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Coverage and Reimbursement Challenges and Strategies

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Disclosures

- Advisory Boards/Consulting- Amgen, Heron Therapeutics, Eli Lilly, Seattle Genetics, Tesaro
- I will be discussing non-FDA approved indications during my presentation---- insofar as they pertain to Prior-Authorization/Pre-Cert issues.

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Medicare

- Most Medicare Administrative Contractors (MAC) have at least one I-O agent Local Coverage Determination (LCD)
- Some MAC have separate LCD for all 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
- Medicare fiscal intermediaries “do not require prior authorization”. Practical impact- prior authorization is not available.

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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 FDA approved Label, and/or NCCN Guidelines and/or ASCO Guidelines and additional criteria which must be met in order to assure reimbursement
  - Example: Anthem clinical policy for nivolumab includes patient's current ECOG score 0-2 be met

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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

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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, often months or > one year post treatment date of service particularly for off-label uses, even when there was a pre-determination in acceptance of the use

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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 (and currently not available)
  - **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

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Denials – common reasons

- Lack of pre-certification or authorization
- Medical necessity– aka “medical necessity as re-defined by that payer
- Experimental and investigational— e.g., treatment that the payer defines as not medically necessary.
- 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
- Insurance duplicity or delay

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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
- Exceeds total units allowable

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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---if not routinely part of the process- constantly available to consult with the Finance Team
  - Ability to learn and understand financial systems and processes
  - Ability to navigate electronic medical record

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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”

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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
    - NCCN Guidelines and Compendia
    - ASCO Guidelines
    - Recent peer reviewed publications- e.g. JCO, JOP, NEJM, etc

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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

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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

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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 (AIM Specialty Health)
    - Current lab and scan results
- Appeal successful and reimbursement granted

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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

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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

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Case Example:

- Final Outcome:
  - The pre-determination was submitted to Aetna
  - Initially the case was denied for experimental and investigational
  - Peer to peer appeal was arranged
  - Denial was over turned
  - Claims were resubmitted
  - Appeal successful and reimbursement granted

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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