ADVANCES IN Cancer IMMUNOTHERAPY™

Coverage and Reimbursement Challenges and Strategies

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Society for Immunotherapy of Cancer

Disclosures

- Merck & Co., Inc., Eisai, Inc., Fees for Non-CME/CE Services Received Directly from a Commercial Interest *or their Agents*
- I will not be discussing non-FDA approved indications during my presentation.

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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

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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 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

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Commercial Payers

- Use of maximum dosages regardless of weight
  - Maximum allowable units per day and per date span for specialty drugs
- Use of National Drug Code (NDC) units versus CPT/Healthcare Common Procedure Coding System (HCPCS) units creates confusion and concern for underpayment
  - J code represents the amount of drug per billing unit
    - 1 J code per medication
    - J code established by CMS
  - NDC represents the manufacturer and size of the vial
    - 1 NDC code for each vial size for each manufacturer
    - NDC code established by FDA and manufacturer
  - Monitor closely for errors in underpayment

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Commercial Payers

- Disproportionate approvals of total billing units versus doses 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

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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 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

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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
- 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
  - 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

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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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Case Example:

- Request for nivolumab 3mg/kg every 2 weeks for NSCLC in July, 2016
- Diagnosis code: 162.9 (ICD 9)
- Insurance: Aetna
- Cost of therapy: $75,064
- FDA approved package insert
- Patient weight: 110kg

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Case Example:

- Initial thoughts?
  - Within indication at time of initiation
- Concern for reimbursement?
  - FDA updated dosing in September 2016
  - 240mg flat dose
- What happened next…
  - October claims denied due to excessive billing units

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Case Example:

- Final Outcome:
  - The pre-determination was submitted to Aetna
  - Case was approved with current FDA approved dose
  - Reimbursement was denied based on dose
  - 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