ICLIO Webinar: Coverage and Reimbursement Case Studies

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Off-Label Disclosure

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

Overview

- Identify the appropriate steps in developing an insurance payer reconsideration for Immuno-Oncology (I-O) products.
- Describe a method that is necessary to prepare, submit, and manage a pre-determination for an I-O product.
- Describe the process to appeal a denied claim for I-O products.
- Describe a process to ensure medication access for I-O agents when faced with an insurance denial.

Common Reason 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

General Rules for Denials

- Discover the root cause of the denial
  - Review payer specific policy, Local Coverage Determination (LCD), National Coverage Determination (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

Case Example 1

- 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 1

- 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 1

- 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 2

- Request for pembrolizumab 2mg/kg every three weeks for metastatic melanoma to lymph node
- Diagnosis code: C77.9
- Insurance: Caresource Medicaid
- Cost of therapy: $155,567
- Level of evidence:
  - FDA approved
  - NCCN supported level 1
  - Clinical policy for payer

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Case Example 2

- Initial thoughts?
  - Case should be approved without issues
- Concern for reimbursement?
  - None
- What happened next…
  - The case was DENIED. Why?
  - Omission of data? Wrong code? Clinical policy outdated?

Case Example 2

- Final outcome
  - Clinical policy was outdated with BRAF testing required and prior ipilimumab therapy
  - Peer to peer needed to be performed
  - No call received from the payer after the peer scheduled
  - Contacted the pharmacy director to get a reconsideration due to outdated policy
- Appeal successful and reimbursement granted

Case Example 3

- Request for nivolumab 3mg/kg every 2 weeks for metastatic melanoma to lymph node
- Diagnosis code: C43.72, C77.8
- Insurance: Original Medicare
- Cost of therapy: $150,129
- Level of evidence:
  - FDA approval
  - NCCN supported Level 1
  - LCD supported diagnosis

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Case Example 3

- Initial thoughts?
  - Case should be approved without issues
  - No ABN needed
- Concern for reimbursement?
  - None
- What happened next…
  - Denied for medical necessity & units of service exceed acceptable maximum
  - Why did this deny?
    - Coding? C43.72, C77.8
    - Dose? Patient weight 160kg = 480mg dose

Case Example 3

- 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
    - Medicare Redetermination Request Form
- Appeal successful and reimbursement granted

New Agents and Off-Label Requests

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Pre-Determination Approaches

- 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

Pre-Determination Basics

- Verify medical insurance
- Obtain copies of pertinent information from patient medical record (treatment plan, diagnostic studies, etc.)
- Retrieve supporting literature
- 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

Case Example 4

- 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 4

- 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 4

- 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

Case Example 5

- Request for nivolumab 3mg/kg every 2 weeks for Stage IV breast cancer
- Diagnosis code: C50.919
- Insurance: Original Medicare
- Cost of therapy: $50,042
- Level of evidence:
  - Diagnosis not supported by the LCD

Case Example 5

- Initial thoughts?
  - Diagnosis not supposed by the LCD
  - No compendia support for diagnosis
- Concern for reimbursement?
  - Medicare will deny the claim
- What happened next…
  - ABN is necessary
  - Submit pharmaceutical access paperwork through BMS

Case Example 5

- Final Outcome
  - Patient was accepted into the BMS Oncology assistance program to receive free medication
  - ABN was delivered to the patient 24 hours prior to therapy

Redetermination Process

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Reshaping Medical Policies

- Request modification of the LCD via a "reconsideration packet"
- Submit request in writing from a physician
- Provide one Phase III or two Phase II (possibly Phase I) clinical trial data from a peer-reviewed journal and published evidence-based guidelines (if available)
- Identify other MACs who reimburse for the indication in question

Case Example 6

- Request to expand the Pembrolizumab Local Coverage Decision (LCD) for Cigna Governmental Services
- Request the expansion to include ICD-10 codes applicable to the treatment of Merkel cell carcinoma (MCC).

Case Example 6

- Initial thoughts?
  - Requests for therapy from prescribers
  - Available evidence
  - Safe or tolerable therapy
- Level of evidence
  - Phase II trial- *N Engl J Med*.2016;374:2542-52. ”PD-1 Blockade with Pembrolizumab in Advanced Merkel-Cell Carcinoma”

Case Example 6

- Final outcome
  - Expansion of the CGS local coverage determination for MCC
  - Addition of thirty ICD-10 codes

Questions?

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

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