# Managing Denials and Appeals

# Common Reasons for Denials

- Lack of precertification or authorization
- Medical necessity
- Experimental and investigational
- Requires additional information
- Non-covered service/medication on the plan benefit
- Out-of-network provider
- Timely filing
- Multiple diagnoses coding for disease states and metastases- payer does not apply correct codes to medications
- Error in number of units billed to payer

# Why Involve Pharmacy?

- Clinical expertise
  - Understanding of mechanism of action (MOA) of medication and how it affects disease
- Often knowledgeable of issue already due to:
  - Pharmacist specialists at point of care working with team
  - Initial involvement with off-label request
- Easier to contact (vs. physicians)
- More payer rules
- More expensive medications
- Outpatient oncology pharmacy should be viewed as a **REVENUE** center

# Handling of Denials

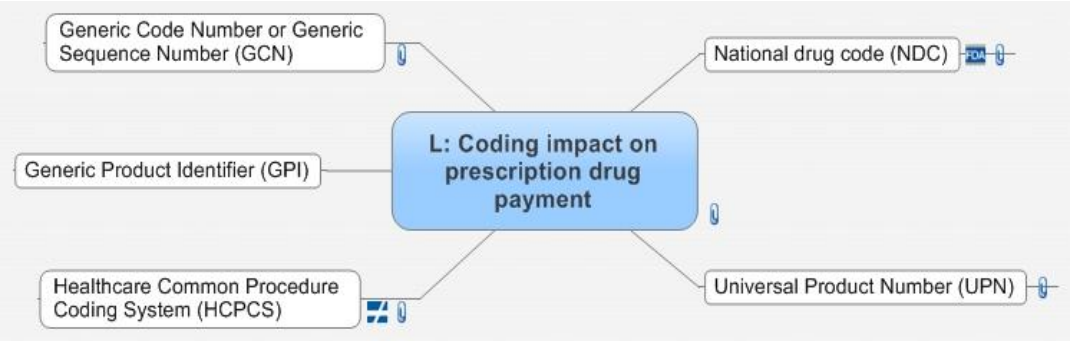
- Work with finance to develop a method for routing denials to appropriate personnel
  - Leverage IT to create work queue and notification process
- Consider appropriateness of resources based on
  - Workload (average number of denials/appeals)
  - Strict appeal timelines of many payers
- Consider training/experience of personnel
  - Ideally a nurse or pharmacist with oncology experience
  - Ability to learn and understand financial systems and processes

# Preparing an Appeal Letter

- Review payer-specific policy, LCD, NCD
- Determine if precertification or prior authorization was completed
  - Approval number and representative name listed
  - Precertification or prior authorization does not guarantee payment
- Review documentation
  - Reimbursement is linked to the quality of the bill
  - Coders obtain information from medical record, but sometimes required information is missing

# Preparing an Appeal Letter

- To determine reason for denial look at:
  - Diagnosis codes
  - Drug codes
  - Units charged
  - Drug administration codes
  - NDC number



# Preparing an Appeal Letter

- Obtain peer-reviewed literature and compendia support
- Gather all the facts in relation to disease and medication(s)
  - Support for specific chemotherapy regimen and usage
  - Applicable medical records such as physician notes, patient labs, scans, and proof of drug orders dispensed and administered to the patient
- Tell the patient's story in a compelling manner

# Preparing an Appeal Letter

- Structure the letter into at least three parts
  - Summary of the request
  - History of the patient's disease including previous treatments
  - Medication MOA and how that impacts the disease (referencing the provided literature)
- Letter should be signed by preparer of the letter (as an agent of the provider)

# Patient Case: On-Label

- Request for pembrolizumab 2mg/kg every three weeks for metastatic melanoma to lymph node (no prior ipilumumab, no BRAF testing done)
- Diagnosis code: C77.9
- Insurance: Caresource
- Cost of therapy: $155,567
- Level of evidence:
  - FDA-approved – ipilumumab trial no longer required, BRAF testing not required
  - NCCN supported level 1
  - Payer has clinical policy for pembrolizumab use

# Patient Case: On-Label

- Initial thoughts?
- Concern for reimbursement?
- Next steps

# Patient Case: On-Label

- Initial thoughts?
  - Case should be approved without issues
- Concern for reimbursement?
  - None
- Next steps
  - Submit precertification
  - Enroll patient in PMAP

# Patient Case: On-Label

- Final outcome
  - Claim denied
    - Clinical policy was outdated with BRAF testing required and prior ipilimumab therapy
  - Payer required a peer-to-peer to be performed
  - Peer-to-peer scheduled, but payer never called during times provided
  - Payer pharmacy director was contacted to request a reconsideration due to outdated policy
  - Denial overturned and patient treated with minimal delay

# Medicare Appeal Process

- Follow same steps listed for “Preparing an Appeal Letter”
- Clinic administrated medications and oral medications have the same Medicare rights to appeal
- Must also abide by CMS Medicare Appeals Guideline
  - **https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/medicareappealsprocess.pdf**

# Sample Appeal Letter

614-293-8470 Phone
614-366-4232 Fax

May 5, 2015

United HealthCare
PO Box 30573
Salt Lake City, UT 84130-0573

RE: Patient Name
DOB: 1/1/1900

ID#99999999
Dates of Service: 11/5/14, 11/26/14, 12/17/14, 1/7/15
Denied Invoice: 635224000, 691941900, 714560000
Reference Number: 1QG32777466, 1QG32851159, 1QG32975443
Item Denied: J9355
Reason for Denial: Medical necessity [50]

Dear Appeals Units,

Please accept this letter as a formal request to file an expedited request in above mentioned claim for to provide medical necessity for the treatment for Patient Name. As documented below, the treatment provided is reasonable and medically necessary for Ms. Patient Name's diagnosis of recurrent metastatic squamous cell salivary duct carcinoma. A request to pre-authorize this therapy was placed and approved to begin therapy (reference#) on 11/1/2014 You will find enclosed peer-reviewed literature, physician's notes, peer reviewed literature, pathology reports, diagnostic, and radiology reports for Ms. Name.

Patient Name was diagnosed with Metastatic recurrent salivary duct carcinoma (stage ypT3N1M1) at an outside facility in February 2002. The initial mass was surgically resected in 2002 and reoccurred in July 2003 which she underwent radiation therapy and cisplatin chemotherapy. Ms. Name had another reoccurrence in June 2012 and underwent surgery, followed by radiation and cetuximab chemotherapy. She underwent another surgical resection of the lung mass in April 2013 that displayed HPV squamous cell carcinoma. In June 2013 scan noted a disease progression in the right parotid which she began taxol, carboplatin and cetuximab. He underwent salvage surgical resection of the right radical parotidectomy and face resection with additional radiation to the tumor bed. Staining of the tumors revealed HER2/Neu (3+ staining) which the plan to treat with taxol, carboplatin and trastuzumab was developed based on peer-reviewed literature in this rare, high grade aggressive tumor.

Salivary gland cancers represent 3-6% of all head and neck cancers and usually present with high grade epithelial malignancy that affect major salivary glands. Therapy is usually reserved with surgical and adjunctive radiation therapy. Trastuzumab, a HER2-directed humanized monoclonal antibody, combined with chemotherapy, significantly improves response rates, time to progression, and overall survival in women with HER2-positive metastatic breast cancer compared with chemotherapy alone. It has been studied in many other disease settings and considering the histopathological similarities between breast cancer and salivary ductal cancer it is a reasonable and effective choice given the patient's over expression of HER-2 marker. Current data indicate that the HER-2 protein is overexpressed in numerous tumor types, including breast, ovary, bladder, salivary gland, endometrium, stomach, pancreas and non-small cell lung cancers. A HER-2 marker is usually an indicator of poor response and can predict the response to therapy and anti-tumor monoclonal antibodies, such as trastuzumab have a therapeutic role in recurrent salivary ductal tumor patients. After reviewing Mrs. Name's records, I believe that the use of the medication is warranted.

I respectfully request that you review the additional documentation provided and evaluate your coverage of these claims. I look forward to your reconsideration. If I can provide any additional information, please contact me at 614-293-4671.

# Reconsideration Process

- Medicare claims for off-label use are more likely to be denied than with commercial payers since no predetermination process exists (i.e., you cannot ask for permission)
- However, a formal process does exist for requesting permission ***unrelated*** to any single patient treatment as deviations from the evidence and/or standard of practice are identified with Medicare and commercial payer policies
  - Deviations may be identified through rejected claims or prospective monitoring of LCDs, NCDs, and payer policies

# Reconsideration Process

- Information provided is similar to an appeal letter
- Assemble a reconsideration packet with all supporting evidence
  - 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)
  - Patient cases where treatment has shown effectiveness may be considered
- For an LCD reconsideration, it's helpful to identify other MACs* who do reimburse for the indication in question

*Medicare Administrative Contractor

# Reconsideration Process

- NCDs are the most difficult to change since they require willingness of CMS to open up for public comment
  - More effective if done in conjunction with professional organizations
- Cover letter should:
    - Succinctly describe the “ask”
    - Be signed by senior physician leader (chief of medicine, physician-in-chief, etc.)
    - Be reviewed by compliance officer

# Sample Reconsideration Letter

May 14, 2013

CGS
Contractor Medical Director
J-15 A/B MAC and HHH LCD Reconsiderations
Two Vantage Way
Nashville, TN 37228

Dear Sir/Madam:

Re: Formal request to reconsider the Local Coverage Determination (LCD) L31836 Chemotherapy and Biologicals for the medication denosumab (Prolia®, Xgeva®, J0897)

The Arthur G. James Cancer Hospital and Richard J. Solove Research Institute is a healthcare provider within CGS Administrators, LLC Jurisdiction 15 (15201, MAC - Part A; 15202). We are requesting a reconsideration of denosumab coverage within the Chemotherapy and Biologicals LCD (L31836). There is no conflicting National Coverage Determination for this medication class.

Denosumab (Prolia®, Xgeva®, J0897) is currently covered within the CGS LCD when used for the treatment of bony metastases (ICD-9-CM code 198.5) and osteoporosis (ICD-9 CM codes 733.00, 733.01, 733.02, 733.09). Based on the support presented below, we request the following addition to the denosumab

LCD coverage:

Use of denosumab to treat bony metastases from neuroendocrine solid tumors be added to the denosumab LCD coverage.Specifically add ICD-9-CM code 209.73 (Secondary neuroendocrine tumor of bone)

**Background**

Denosumab (Xgeva®) is U.S. Food and Drug Administration (FDA) approved for the prevention of skeletal-related events in patients with bone metastases from solid tumors.

Neuroendocrine tumors are solid tumors characterized by having special secretory granules that often produce a variety of amine and peptides that can cause characteristic hormonal syndromes. While primary neuroendocrine tumor sites typically occur in organs such as the intestine and lungs, they can metastasize to bony tissue. As reported in the Centers for Disease Control and Prevention ICD-10-CM Coordination and Maintenance Committee Meetings notes, due to the unique characteristics of this disease, it was requested that distinct ICD-10-CM categories be created to specifically identify malignant and benign neuroendocrine tumors and Merkel cell cancers.[1]

Consistent with the Centers for Disease Control and Prevention, it is appropriate to code for neuroendocrine bone metastases with ICD-9-CM code 209.73 as opposed to ICD-9-CM code 195.8.

**Supporting Clinical Evidence**

Denosumab has been shown in several well designed trials to reduce the incidence and morbidity of skeletal-related events in patients with solid tumor bone metastases.[2,3] While the benefits of denosumab therapy have been established in breast cancer, prostate cancer, lung cancer, and other advanced cancer patients with bone metastases, denosumab has not specifically been studied in patients with neuroendocrine bone metastases.

**Authoritative Drug Compendia**

Recommendation summaries for denosumab taken from drug compendia recognized by The Centers for Medicare & Medicaid Services:

NCCN Drugs & Biologics Drug Compendium:

Consider for supportive therapy in patients with bone metastases for several diseases but neuroendocrine bony metastases are not specifically mentioned. NCCN category: 2A

Thomson's Micromedex DrugDex:

Bone metastasis, Associated with Solid Tumors - Disorder of skeletal system; Prophylaxis. Neuroendocrine bony metastases are not specifically mentioned Recommendation: Class IIb.

**Excerpts of coverage provided by other MACs**

Provide coverage for the prevention of skeletal–related events in patients with bone metastasis from solid tumors but do not specifically mention or include ICD-9 code 209.73 for neuroendocrine bony metastases

**Summary**

Use of denosumab (Xgeva®) to reduce skeletal complications of solid tumor bone metastases is supported by the FDA, peer reviewed literature, and Centers for Medicare & Medicaid Services recognized compendia. In response to a specific request, neuroendocrine tumors, including bony metastatic sites, have been assigned distinct ICD-10-CM codes. To be able to provide denosumab's prevention of skeletal-related events benefits to patients with neuroendocrine bone metastases, it is requested that CGS add ICD-9-CM code 209.73 to the denosumab LCD.

Sincerely, Senior Leader Information and signature


Denosumab (Xgeva®) package insert. Amgen, Inc. February 2013.

Centers for Disease Control and Prevention ICD-9-CM Coordination and Maintenance Committee Meeting September 24-25, 2008 Diagnosis Agenda

Centers for Disease Control and Prevention ICD-9-CM Coordination and Maintenance Committee Meeting September 27-28, 2007 Diagnosis Agenda

Stopeck AT, Lipton A, Body J-J et al. Denosumab compared with zoledronic acid for the treatment of bone metastases in patients with advanced breast cancer: a randomized, double-blind study. J Clin Oncol 2010; 28:5132-5139.

Fizazi K, Carducci M, Smith M et al. Denosumab versus zoledronic acid for treatment of bone metastases in men with castration-resistant prostate cancer: a randomized, double-blind study. Lancet 2011; 377:813-822.

Henry DH, Costa L, Goldwasser F et al. Randomized, double-blind study of denosumab versus zoledronic acid in the treatment of bone metastases in patients with advanced cancer 9excluding breast and prostate cancer) or multiple myeloma. J Clin Oncol 2011; 29:1125-1132.

NCCN Drugs & Biologics Compendium. Denosumab accessed 5/10/13.

Micromedex Drugdex. Denosumab accessed 5/10/13.

# Appeal Process for Orals

- Process is the same as preparing an appeal letter for an infused agent
- However, it must be completed before the patient receives the medication
- Leverage pharmaceutical assistance programs
  - May provide additional literature to assist with appeal
  - Quick start programs are available but should be carefully considered

# Tips for Success

- Build relationships with key departments (Managed Care and Revenue Cycle) to assist with difficult cases
  - Research payment inconsistencies such as splitting dose of medication
- Build relationship with finance personnel communicating with payers
  - Share identified trends to be elevated with specific payer when denial patterns are identified
    - Example: Information provided to payer too repeatedly is lost or they continually state it was never received
  - Ideally have a pharmacy representative at routine payer meetings to address coverage concerns

# Tips for Success

- Follow the appeal
  - Work with finance to ensure any ***denied appeal*** is also routed back to the denial work queue (or minimally that notification is received by pharmacy)

- Understand appeals process for various payers
  - Medicare- five levels of appeal
  - Commercial- usually two levels of appeal

# Tips for Success

- Learn from past denials
  - Share denial information with providers at Pharmacy and Therapeutics Committee or other forum to determine next steps
    - Policy or practice change
  - Use reconsideration process to avoid future denials
- Leverage available pharmaceutical reimbursement assistance programs
  - Many provide assistance starting with initial benefits investigation up through all levels of appeal

# Types of Pharmaceutical Manufacturer Reimbursement Assistance

- Benefits investigation
  - Full patient benefits investigation for coverage and patient out-of-pocket
  - Provide prior authorization requirements for medication
- Appeals assistance support
  - Follow claims before and after denials are appealed
  - Provide literature for use in appeal
  - Arrange peer-to-peer with provider and payer if needed
- Referral to Pharmaceutical Manufacturers Assistance Program (PMAP) for replacement
  - Provide replacement medication for off-label indications depending on diagnosis
- Referral to cost sharing programs/copay assistance programs

# Types of Pharmaceutical Manufacturer Reimbursement Assistance

| Company | Services |
|---|---|
| Amgen | A B DxA CA |
| Aventis | B DxA CA |
| Merck | A B DxB CA |
| BMS | A B DxB CA |
| Celgene | A B DxB CA |
| Genentech | A B DxB CA |

| Company | Services |
|---|---|
| Lilly | A B DxA CA |
| SeaGen | A B DxA CA |
| Novartis | B DxA CA |

**Table of Contents**

**A= Appeals assistance**

**B= Benefits investigation**

**DxA= Specific dx not considered for PMAP replacement after denial**

**DxA = Replacement for PMAP; Independent of diagnosis**

**CA= Cost sharing assistance/co-pay assistance referrals**

# Questions?