Putting the Pieces Together, a Review of the Benefits Investigation Process

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Introductions

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Agenda

• Overview – Thomas Cohn
• Background on Coverage Policy – Connie Inguanti
• Background on Prior Authorization & Standards – Tony Scheuth
• Panel Questions / Discussion
  – Thomas Cohn (Moderator)
  – Connie Inguanti
  – Tony Scheuth
  – Caleb DesRosiers
Putting the pieces together

Coverage Policy

PA's

Develops

PBM's

Services

BIN/PCN, NDC

Pharmacy Claims

Medical Claims

Patient Eligibility

Pharmacy

Risk

Plan Sponsors

Contract

Jcode

Health Plan’s

Contract

Develops

Develops
The Role of Payer Coverage Policy in Benefit Verification
Organized health care delivery system

• Designed to improve the quality and accessibility of health care . . .

• Including pharmaceutical care . . .

• While containing costs . . .

• By putting limited resources to best use in patient care
Managed Care Pharmacy

Ensures access to clinically sound, cost-effective medications, biologics and devices for patients/members

• Pharmacy & Therapeutics (P&T) committees
  – Pharmacists
  – Physicians, including specialist advisors
  – Others (representing Administration, Contracting, Legal, etc.)

• Develop and manage:
  – Formularies
  – Practices and policies related to access, reimbursement & appropriate use

• Responsible for traditional retail drugs and “medical” or “specialty” drugs
Drug Access & Reimbursement Requirements

All P&T-required conditions must be met for successful benefit verification and approval at the pharmacy fulfillment level

• Pharmacy management tactics:
  – Formularies
  ➢ Prior Authorization (PA), step edits, restrictions
  ➢ Coverage/medical policy
  – Benefit design
  – Contracting
  – Pharmacy networks, mail order, specialty pharmacies
  – Disease management
  – Drug utilization review
  – Outcomes research
  – Patient and provider education
“Appropriate use” is the objective of P&T drug-related practices & policies

• Right drug to the right person at the right time

• Aligned with formulary & contracting

• Aligned with P&T committee/medical department’s determination of best clinical practices
  
  − Often apply to high-cost specialty drugs for complex disease states
  
  − Formulary measures include PA, ST and other restrictions
  
  − **Coverage/medical policy**: Detailed medical conditions that must be met for reimbursement, e.g., diagnosis, documentation of previous treatment, documented genetic marker if for a targeted therapy
Coverage Policy is the Foundation of Benefit Verification/Approval at the Pharmacy Level

- Coverage Policy
  - Medical requirements/best practices
- PA Form
  - Ensures necessary requirements are met
- Approval
In this example, Pfizer’s oral chemotherapy Xalkori is indicated to treat non-small cell lung cancer in patients with specific gene expressions.

**INDICATIONS AND USAGE**

XALKORI is a kinase inhibitor indicated for the treatment of patients with:
- metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test. (1.1)
- metastatic NSCLC whose tumors are ROS1-positive. (1.2)

**DOSAGE AND ADMINISTRATION**

- Recommended Dose: 250 mg orally, twice daily. (2.2)
- Renal Impairment: 250 mg orally, once daily in patients with severe renal impairment (creatinine clearance <30 mL/min) not requiring dialysis. (2.2)
Coverage Policy Criteria: Example

• Here, the health plan’s Coverage Policy states that use is approved if the patient has one of the FDA-approved indications AND that it is documented by a genetic test

• Criteria for allowed off-label uses may also be listed – common with cancers, based on national guidelines or clinical trial data

APPROVAL CRITERIA

Requests for Xalkori (crizotinib) may be approved for the following indications, when accompanying criteria are met:

I. Non-small cell lung cancer (NSCLC), recurrent or metastatic; **AND**
   a. Documentation is provided that tumor is documented anaplastic lymphoma kinase (ALK)-positive; **OR**
   b. Tumor is documented as c-ros oncogene 1 (ROS1) positive (NCCN); **OR**
   c. Mesenchymal-Epidermal Transition (MET) amplifications are present (NCCN);

II. Inflammatory Myofibroblastic Tumor (IMT) with ALK translocation (NCCN).
This plan’s PA form reflects its Coverage Policy criteria. For use to be approved at the pharmacy level, the physician must document:

- An approvable diagnosis (in this case, associated with a gene expression)
- Documentation that an FDA-approved genetic test was done (per FDA label)
- This plan requires test results to be attached
- Quantity prescribed must align with the plan’s Coverage Policy criteria

If all Coverage Policy criteria are met and documented in the PA form, use will be approved. Otherwise, it will be rejected. A medical exception can be requested.
BusinessOne’s Managed Markets Access Data

**BusinessOne Technology: Coverage Policy Platform**

Deeper dive into access & reimbursement

- 360 degree coverage of Retail and Specialty, Hybrid market
- 85 data elements captured for streamline data analysis
- Medical and Pharmacy prior authorization forms
- Prior Authorization, Step Therapy, & Diagnostic Requirements
- Specialty Pharmacy affiliations
- Coverage Policy for 140 drugs across 40 indications
- Custom Payor segmentation and Market basket scoring
## Coverage Policy Data

<table>
<thead>
<tr>
<th>Policy Specifications</th>
<th>Policy history, health plans/drugs/indications affiliated with the policy.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reimbursement &amp; Guidelines</td>
<td>Reimbursement codes, Rx filling requirements, clinical resources used to create the policy criteria.</td>
</tr>
<tr>
<td>Approved Use</td>
<td>Patient profile, drugs/therapies that can and cannot be used with the drug/device.</td>
</tr>
<tr>
<td>Diagnostic Requirements</td>
<td>Diagnostics that must be performed &amp;/or conditions that must be present for initial and continued use.</td>
</tr>
<tr>
<td>Step Therapy</td>
<td>Required pre-requisite drugs/therapies that must be used prior to the initial request.</td>
</tr>
<tr>
<td>Dosage &amp; Administration</td>
<td>Dosage, frequency, and administration requirements for a specific indication.</td>
</tr>
<tr>
<td>Prior Authorization</td>
<td>Duration limits, documentation, and prescribing specialist related to the initial and recertification requests.</td>
</tr>
</tbody>
</table>
Aggregated executive level reporting of Detail, Scoring, and Segmentation report results.

Therapeutic Markets are compared and scored either advantaged, disadvantaged, or in parity.

Drugs are categorized as Less, Moderately, or Highly Managed at each payer.

The policy entered data.
## Plan Segmentation Criteria

### Degree of Restrictions

<table>
<thead>
<tr>
<th>Plan Segmentation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1 – Open/Less Managed</strong></td>
<td>Includes all 3 below:</td>
</tr>
<tr>
<td>a)</td>
<td>No prior authorization, step requirement, or quantity limit <strong>AND</strong></td>
</tr>
<tr>
<td>b)</td>
<td>No % coinsurance</td>
</tr>
<tr>
<td><strong>2 – Moderately Managed</strong></td>
<td>Any of the following but nothing else:</td>
</tr>
<tr>
<td>a)</td>
<td>Prior authorization but no quantity limit or step requirement <strong>AND/OR</strong></td>
</tr>
<tr>
<td>b)</td>
<td>Specialist use only</td>
</tr>
<tr>
<td><strong>3 – Highly Managed</strong></td>
<td>Any of the following:</td>
</tr>
<tr>
<td>a)</td>
<td>Prior authorization with step requirement <strong>AND/OR</strong></td>
</tr>
<tr>
<td>b)</td>
<td>Prior authorization with quantity limit <strong>AND/OR</strong></td>
</tr>
<tr>
<td><strong>4 - Not Covered</strong></td>
<td></td>
</tr>
</tbody>
</table>

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*Business One Technologies - The Power of One*
Eligibility and PA in Specialty Pharmacy
Drug Coverage – Medical vs Rx Spending

Drugs are Covered Under the:

Medical Benefits

53%

Medical Specialty Spending (2012)

- Other
- Prostacyclins
- Colony Stim Factors
- Interferons
- TNF Inhibitors

Pharmacy Specialty Spending (2012)

- Other
- Antivirals
- Prostacyclins
- Colony Stim Factors
- Interferons

Source: Milliman
The Differences Between Medical and Pharmacy Benefit

**Medical Benefit**

- **Administration**: Intravenous infusions, injections.
- **Dispensing channel**: Physician, infusion center, home health.
- **Billing term**: "Buy and Bill"
- **Claims submission**: Batch or real-time using HCPCS codes.
- **Utilization management**: PA /medical review process
- **Member cost-share**: Copayment for office visit, coinsurance for drug product.

**Pharmacy Benefit**

- **Administration**: Self-administered injections.
- **Dispensing channel**: Specialty pharmacy dispenses drug and delivers to patient.
- **Billing term**: "Bill and Dispense"
- **Claims submission**: Online using NDC.
- **Utilization management**: PA, step therapies, concurrent DUR, formularies.
- **Member cost-share**: Copayment or coinsurance for drug.

**Technology Can Bridge:**

- Software/Tools
- Criteria
- Route down Medical or Pharmacy benefit
Why Prior Authorization?

Payers say that prior authorization provide **cost savings** to consumers by **preventing unnecessary prescribing** of expensive brand name drugs when an appropriate generic is available and to help **prevent drug interactions**

Nearly **40%** of PA requests are **abandoned** due to complex procedures and policies and nearly **70%** of patients encountering paper-based PA requests to **not receive** the original prescription

Source: Cover MyMeds and Frost & Sullivan
A CoverMyMeds study indicated that in 2014 74,400,000 prescriptions were abandoned.

The Administration on Aging projects an increase in PA volume of 20% annually.

*https://epascorecard.covermymeds.com/