specialty pharmacy summit® 2016

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

Thomas Cohn, Asembia

Introductions

Thomas Cohn

Chief Strategy Officer

Asembia

Tony Scheuth

CEO and Managing Partner

Point-of-Care Partners, LLC

Connie Inguanti, R.Ph.

Vice President, Market Access & Strategy

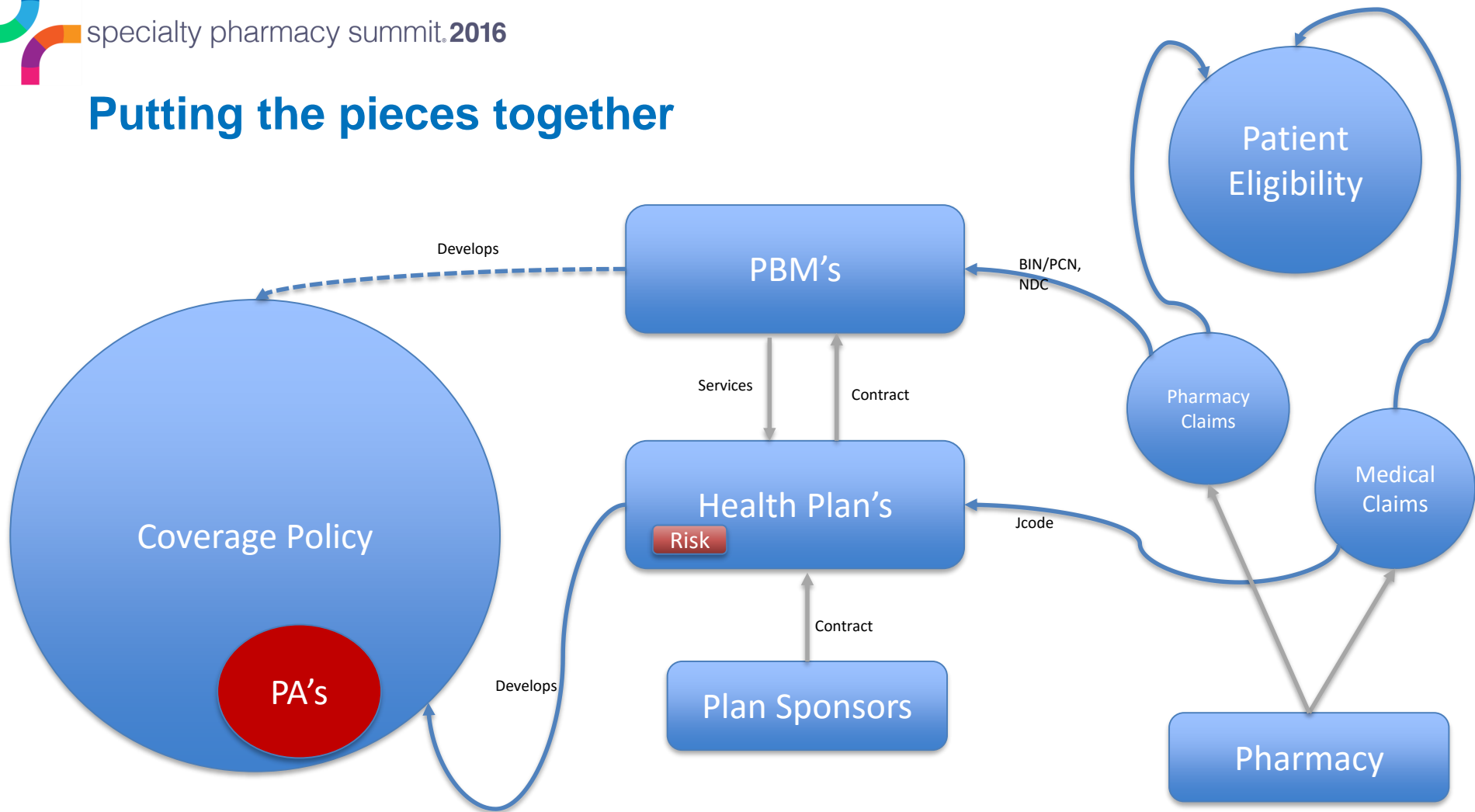BusinessOne Technologies

Caleb DesRosiers, MPA, JD

EVP, Payer Relations & General Counsel

CareMed Specialty Pharmacy

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

Patient Eligibility

PBM's

Develops

BIN/PCN, NDC

Coverage Policy

PA's

Services

Contract

Pharmacy Claims

Medical Claims

Health Plan's

Risk

Jcode

Develops

Contract

Plan Sponsors

Pharmacy

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

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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
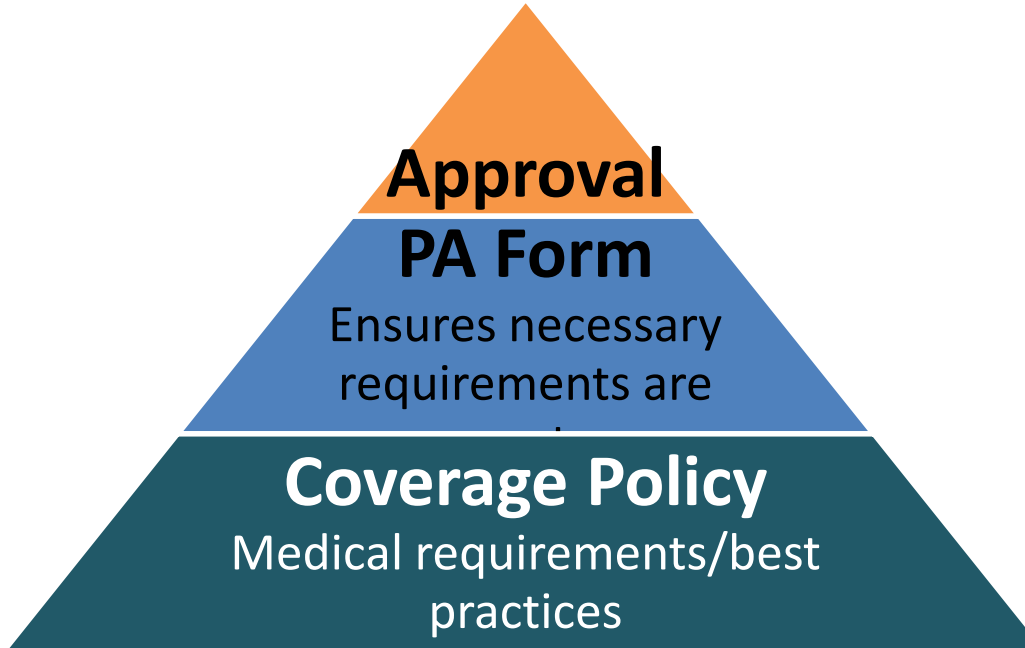
- Pharmacy management tactics:
    - Formularies
    - **Prior Authorization (PA), step edits, restrictions**
    - **Coverage/medical policy**
    - Benefit design
    - Contracting
    - Pharmacy networks, mail order, specialty pharmacies
    - Disease management
    - Drug utilization review
    - Outcomes research
    - Patient and provider education

Coverage/Medical Policy

"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**

Approval

PA Form

Ensures necessary
requirements are

Coverage Policy

Medical requirements/best
practices

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Coverage Policy & PA : Determine Drug Eligibility

- 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

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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).

Coverage Policy Criteria on PA Form: Example

- 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 rejected. A medical exception can be requested.**

CONTAINS CONFIDENTIAL PATIENT INFORMATION
Xalkori (crizotinib)
Prior Authorization of Benefits (PAB) Form
Complete form in its entirety and fax to:
Prior Authorization of Benefits Center

1. PATIENT INFORMATION

Patient Name:
Patient ID #:
Patient DOB:
Date of Rx:
Patient Phone #:
Patient Email Address:

2. PHYSICIAN INFORMATION

Prescribing Physician:
Physician Address:
Physician Phone #:
Physician Fax #:
Physician Specialty:
Physician DEA:
Physician NPI #:
Physician Email Address:

3. MEDICATION — Xalkori (crizotinib)
4. STRENGTH — □ 200mg □ 250mg
5. DIRECTIONS
6. QUANTITY PER 30 DAY — Specify:

7. DIAGNOSIS:

8. APPROVAL CRITERIA: CHECK ALL BOXES THAT APPLY
NOTE: Any areas not filled out are considered not applicable to your patient & MAY AFFECT THE OUTCOME of this request.

□ Yes □ No   Does the patient have a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC)? *If yes:*

□ Yes □ No   Has that patient had a documented anaplastic lymphoma kinase (ALK)-positive result as detected by an FDA-approved companion diagnostic test* (that is, Vysis ALK Break Apart FISH Probe Kit)?

□ Yes □ No   Does the patient have a diagnosis of Inflammatory Myofibroblastic Tumor (IMT) with ALK translocation? *If yes:*

□ Yes □ No   Is the patient using Xalkori (crizotinib) as single-agent therapy?

* A copy of the test results from the FDA-approved companion diagnostic test must be provided

9. PHYSICIAN SIGNATURE

Prescriber or Authorized Signature   Date
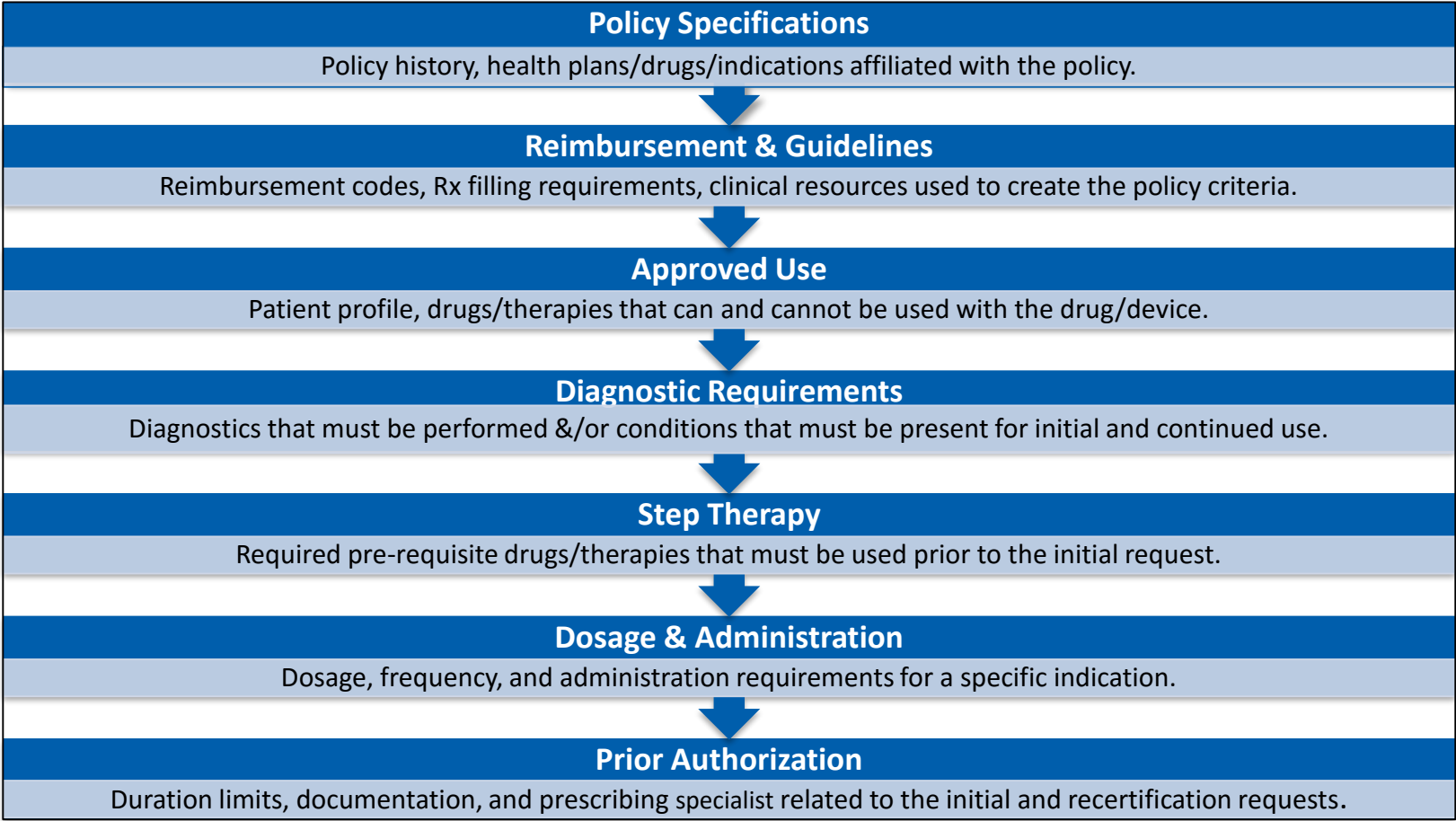
BusinessOne's Managed Markets Access Data

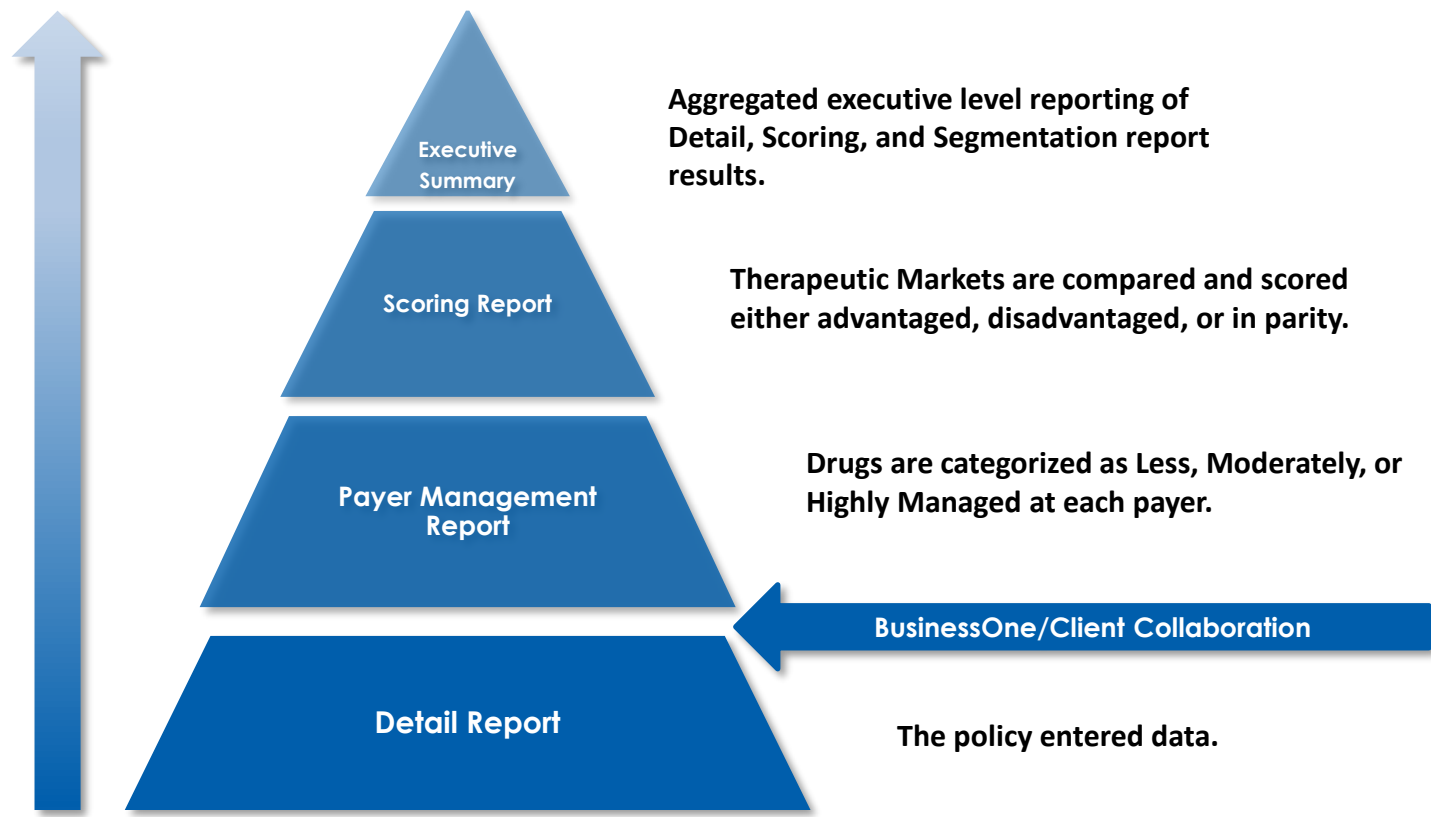**BusinessOne Technology: Coverage Policy Platform**

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
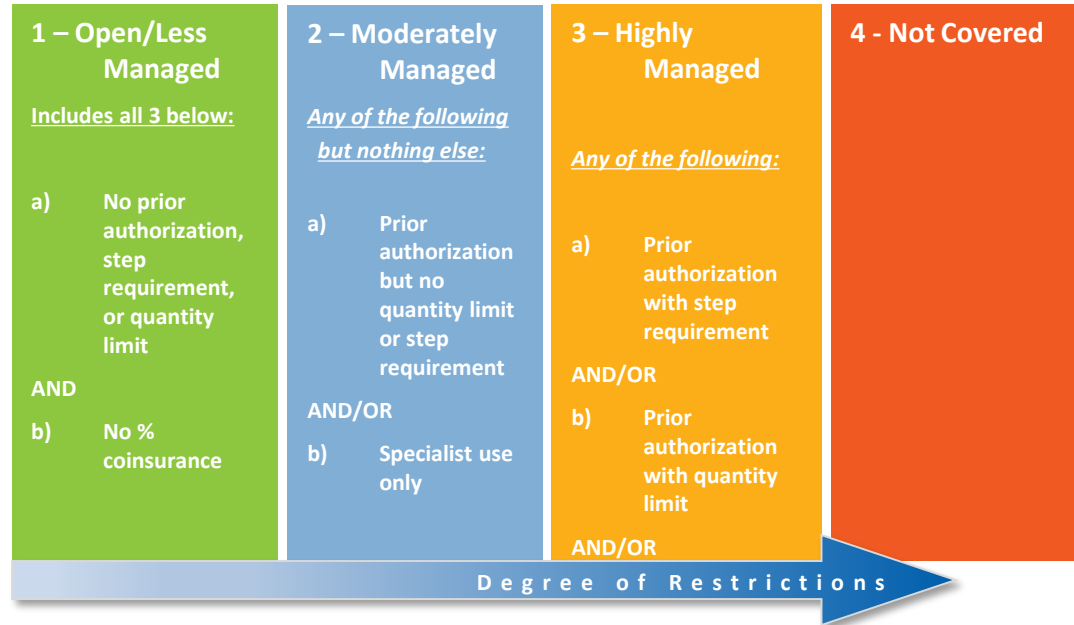- Custom Payor segmentation and Market basket scoring

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Coverage Policy Data

Policy Specifications
Policy history, health plans/drugs/indications affiliated with the policy.

Reimbursement & Guidelines
Reimbursement codes, Rx filling requirements, clinical resources used to create the policy criteria.

Approved Use
Patient profile, drugs/therapies that can and cannot be used with the drug/device.

Diagnostic Requirements
Diagnostics that must be performed &/or conditions that must be present for initial and continued use.

Step Therapy
Required pre-requisite drugs/therapies that must be used prior to the initial request.

Dosage & Administration
Dosage, frequency, and administration requirements for a specific indication.

Prior Authorization
Duration limits, documentation, and prescribing specialist related to the initial and recertification requests.

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Coverage Policy Development Process

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.

BusinessOne/Client Collaboration

The policy entered data.

Executive Summary

Scoring Report

Payer Management Report

Detail Report

Plan Segmentation Criteria

1 – Open/Less Managed	2 – Moderately Managed	3 – Highly Managed	4 - Not Covered
Includes all 3 below:	***Any of the following but nothing else:***	***Any of the following:***	
a) No prior authorization, step requirement, or quantity limit	a) Prior authorization but no quantity limit or step requirement	a) Prior authorization with step requirement	
AND	AND/OR	AND/OR	
b) No % coinsurance	b) Specialist use only	b) Prior authorization with quantity limit	
		AND/OR	

Degree of Restrictions →

Eligibility and PA in Specialty Pharmacy

Drug Coverage – Medical vs Rx Spending
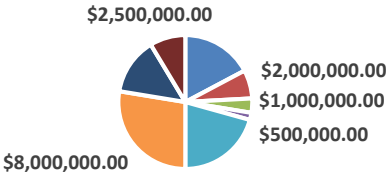
Drugs are Covered Under the:

- Medical Benefits

47%

53%

Medical Specialty Spending (2012)

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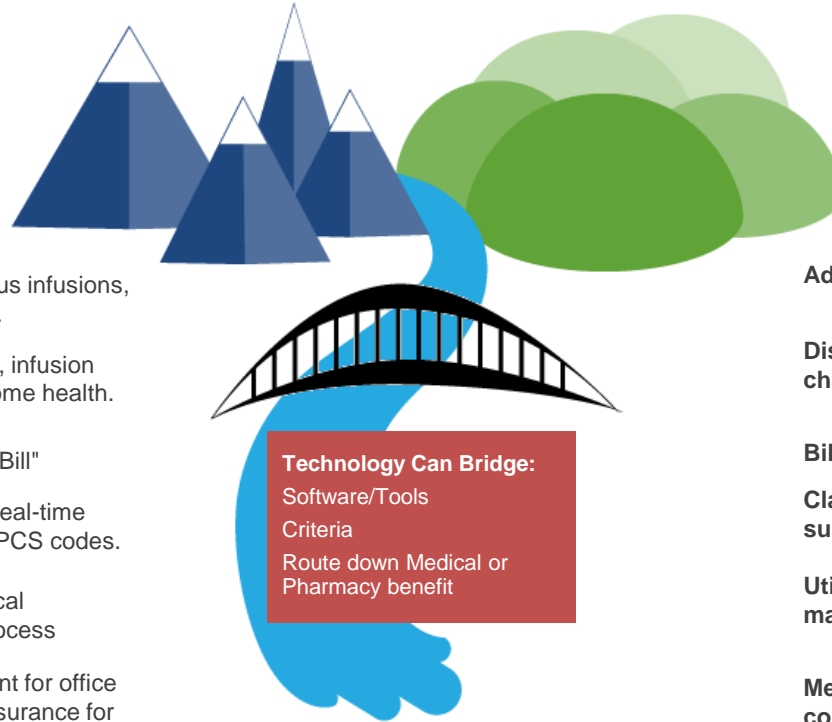- Colony Stim Factors
- Interferons
- TNF Inhibitors

$2,500,000.00 $2,000,000.00

$2,500,000.00

$500,000.00

$13,500,000.00

Pharmacy Specialty Spending (2012)

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

$2,500,000.00

$2,000,000.00

$1,000,000.00

$500,000.00

$8,000,000.00

Source: Milliman

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The Differences Between Medical and Pharmacy Benefit

Medical Benefit

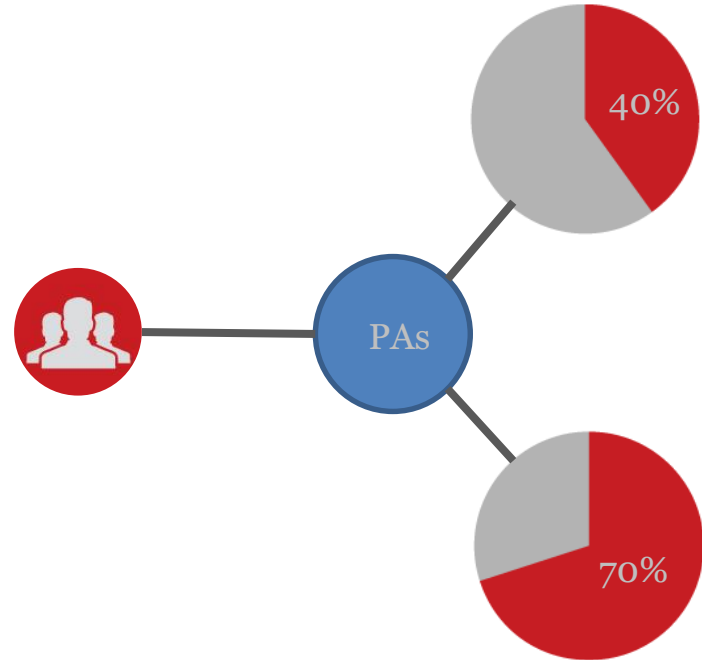|	
Administration	Intravenous infusions, injections.
Dispensing channel	Physician, infusion center, home health.
Billing term	"Buy and Bill"
Claims submission	Batch or real-time using HCPCS codes.
Utilization management	PA /medical review process
Member cost-share	Copayment for office visit, coinsurance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

40%

PAs

70%

Source: Cover MyMeds and Frost & Sullivan
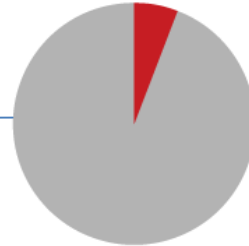https://epascorecard.covermymeds.com/images/FrostSullivanPrior%20AuthorizationWhitepaper%20FINAL.pdf

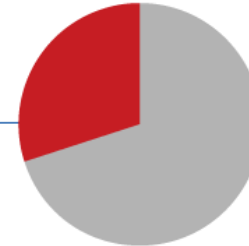21

Consequences of Prior Authorization

A CoverMyMeds study indicated that in 2014 **74,400,000** prescriptions were **abandoned**
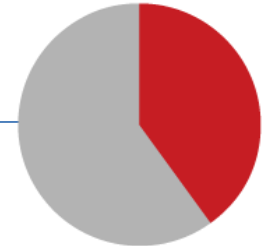
2014
4.4 Billion Annual Prescriptions

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

6%
265 Million Prescriptions Rejected

94%
4.2 Million Prescriptions Filled

70%
186 Million Requiring PA requests

30%
80 Million Resolved at Pharmacy

40%
74.4 Million Abandoned

Due to complex policies and procedures

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