# Navigating Immuno-Oncology Coverage & Reimbursement Issues

**Niesha Griffith, RPh, MS, FASHP**
Administrator of Oncology Pharmacy and Infusion Services at the Arthur G. James Cancer Hospital and Richard J. Solove Research Institute at The Ohio State University

**Bill McGivney, PhD**
Principal of McGivney Global Advisors

**August 27, 2015**
**12 -1 p.m. EST**

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AN INSTITUTE OF ACCC
Association of Community Cancer Centers

ICLIO e-Course 03

# e-Course Overview

**Section 1:**
Bill McGivney, PhD
•General Environment in Coverage and Reimbursement
•Determination of Coverage and Reimbursement for I-O Agents
•Compendia
•Present Coverage for I-O agents
•Impact of new Oncology Value Metrics

**Section 2**
Niesha Griffith, RPh, MS, FASHP
•Institutional Considerations and Needs in Coverage and Reimbursement
•Assurance of explicit, timely, and clear coverage policies including off-label use
•Internal demand for use of I-O agents
•Reimbursement issues

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# Bill McGivney, PhD

*McGivney Global Advisors*

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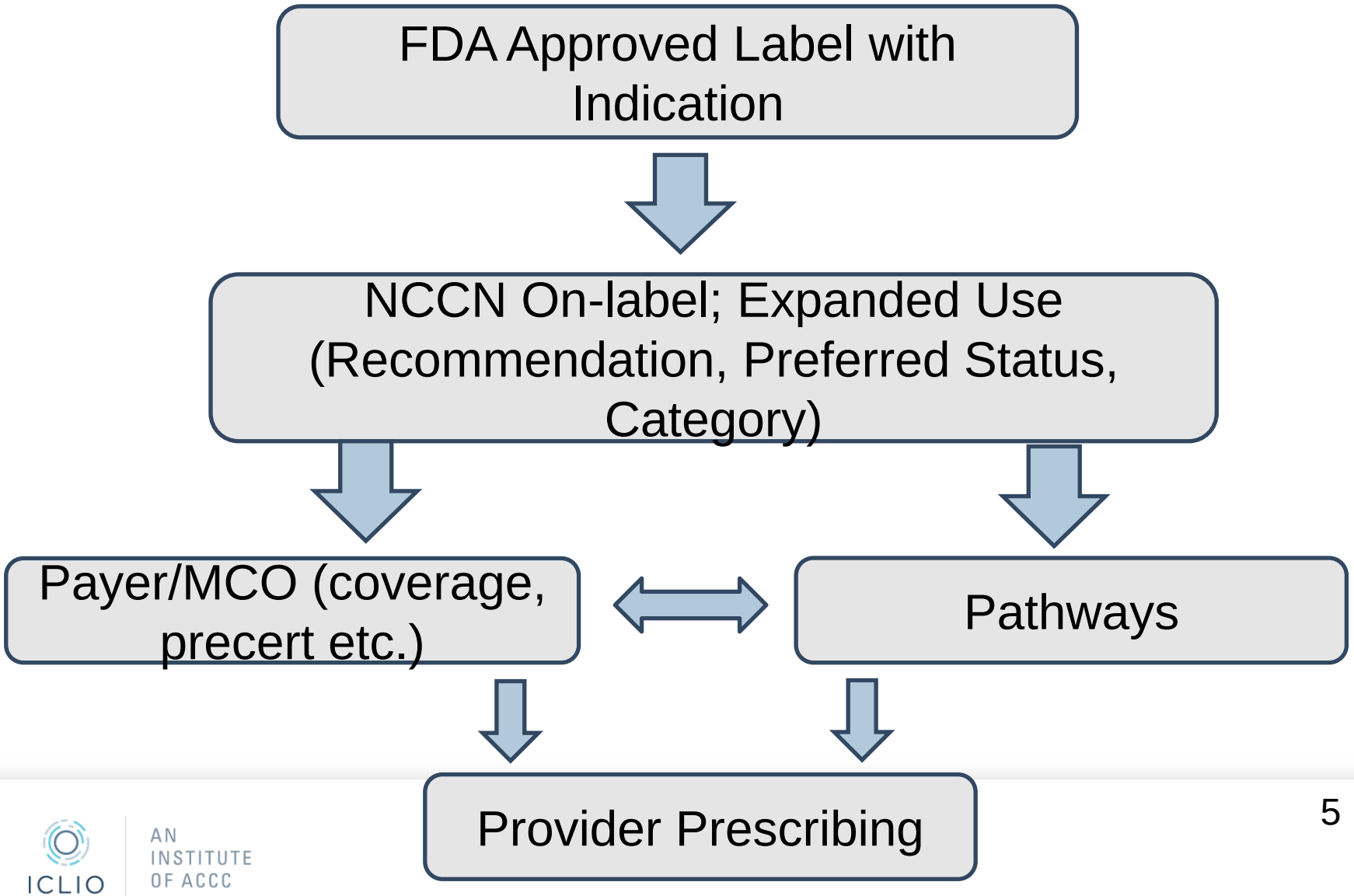
# How Did We Get Here?

## From "Medically-Accepted" to "Outcomes-Based" Coverage Policy

- ***1991:*** Aetna rewrites contractual language, makes outcomes-based, and files in most states
- Payers elevate coverage policies and institute precert programs
- The HDCT/ABMT Battle
  - Payers back off cancer care: Providers, "60 Minutes", Employers and the Courts ($120 million)
- ***2004****: "*Cost of Chemotherapy for Cancer*"* (Schrag, *NEJM* 2004); "financial toxicity" (Saltz)
- **Is $100,000 now the pricing floor? Payers now must control and manage drugs and biologics.**

# Policy-Setting and Decision-Making “FlowDown”



# NCCN Guidelines and Other Information Products

**1996**

- *NCCN Guidelines* launched at NCCN Annual Conference
- NCCN International Collaboration begins in China
- *NCCN Patient Guidelines* Launched
- *NCCN Drugs and Biologics Compendium* launched
- *NCCN Order Templates* Launched

**2012**

- *NCCN BioMarkers Compendium* Launched

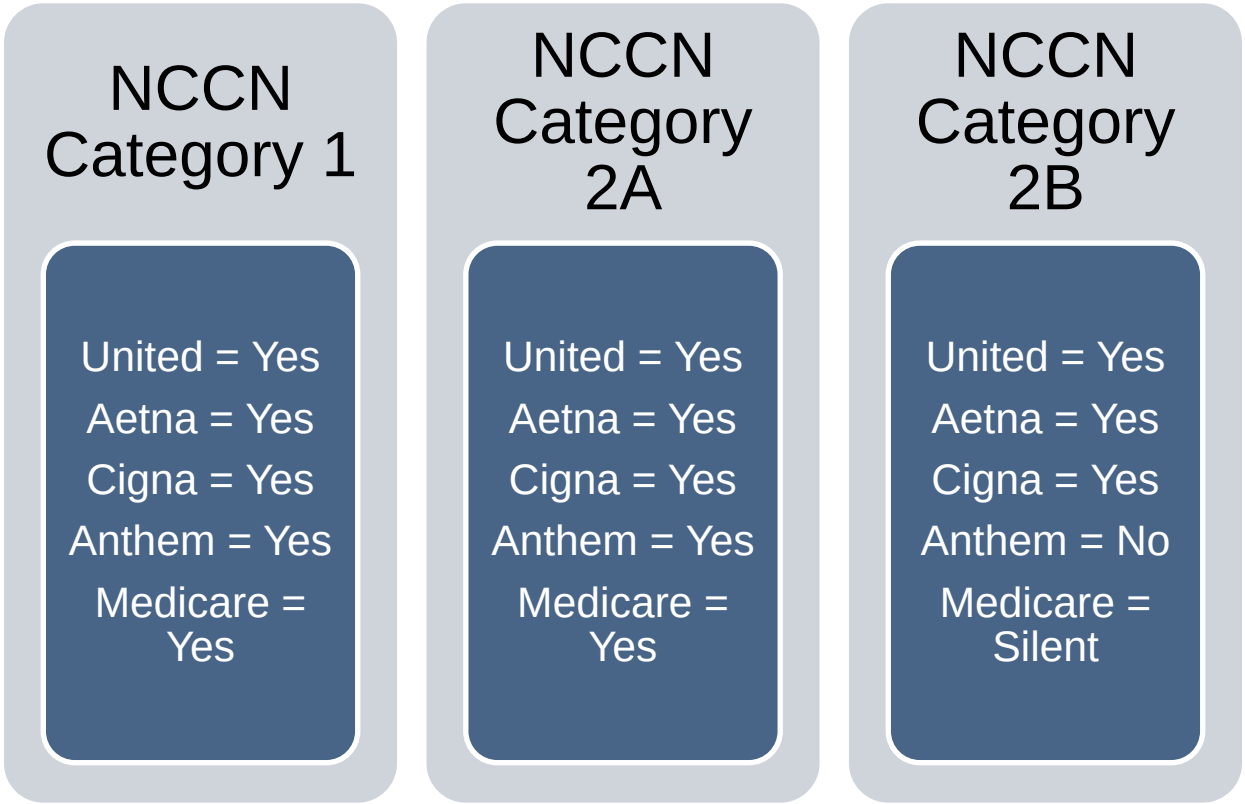
# 2008: A Win for Oncology Providers and Patients

- **Jan, 16 2008 – United Press Release:** If it is in *NCCN Compendium*, we pay for it!
- **June 5, 2008 (4:16pm):** CMS recognizes the *NCCN Compendium*
- The *NCCN Compendium* becomes the critically important to oncologists, cancer patients and biopharma companies
- **Sept 30, 2014:** CIGNA confirmation still using *NCCN Compendium*
- **The *NCCN Compendium* flipped cancer decision-making 180 degrees**

# NCCN Categories

| Quality of Evidence | Level of Consensus | NCCN Category |
|---|---|---|
| High (e.g. RCT, MA) | Uniform | 1 (6%) |
| Lower (e.g. single arm) | Uniform | 2A (87%) |
| Lower (e.g. cohort analysis) | Consensus | 2B (6%) |
| Any (e.g. RCT, single arm) | Major disagreement | 3 (rare) |

# NCCN Categories and Payer Response



# United HealthCare: Medical Benefit

## *Description:*

- This policy provides parameters for coverage of injectable oncology medications (J9000 - J9999) and select other medications used for oncology conditions [including, but not limited to octreotide acetate (J2353 and J2354) and leuprolide acetate (J1950)] covered under the medical benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium™. The Compendium lists the appropriate drugs and biologics for specific cancers using US Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category.

## *Coverage Rationale:*

- UnitedHealthcare recognizes indications and uses of injectable oncology medications listed in the NCCN Drugs and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and Categories of Evidence and Consensus of 3 as unproven. (However, see below for Benefit Considerations.)

# United HealthCare: Pharmacy Benefit

- This policy provides parameters for coverage of specific oral oncology medications covered under the pharmacy benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium™. The Compendium lists the appropriate drugs and biologics for specific cancers using US Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category.

- UnitedHealthcare recognizes indications and uses of oral oncology medications listed in the NCCN Drugs and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and Categories of Evidence and Consensus of 3 as unproven

# Oncology Drug/Biologic Compendia recognized by Payers

| | AHFS® DI | Clinical Pharmacology | DrugDex® | NCCN |
|---|---|---|---|---|
| UnitedHealthcare | √ | √ | √ | √ |
| Humana | √ | √ | √ | √ |
| aetna | √ | √ | √ | √ |
| Anthem BlueCross BlueShield | √ | | √ | √ |
| Cigna | | | | √ |

*Compendia listed above are recognized by Medicare Parts B & D;*

*Medicaid recognizes AHFS DI and DrugDex*

# Aetna Coverage Policy for Nivolumab and Pembrolizumab **(as of August 12, 2015 )**

- Nivolumab** (last Aetna review April 10, 2015)
  - Covered for incompletely resected or unresectable metastatic or recurrent melanoma
  - Covered for squamous NSCLC with progression on or after chemotherapy
  - ***Requires preauthorization*
- Pembrolizumab (last Aetna review April 10, 2015)
  - Covered for incompletely resected or unresectable metastatic or recurrent melanoma

# Anthem Coverage Policy for Nivolumab and Pembrolizumab

**(as of August 12, 2015 )**

- Nivolumab (last Anthem review August 6, 2015)

  Covered for incompletely resected or unresectable metastatic or recurrent melanoma in first line either as monotherapy or in combination with ipilumumab (before NCCN) and as monotherapy for second line or subsequent therapy for documented disease progression

  Covered for squamous NSCLC with progression on or after chemotherapy

- Pembrolizumab (last Anthem review May 7, 2015)

  Covered for incompletely resected or unresectable metastatic or recurrent melanoma as monotherapy in first-line or subsequent therapy for documented disease progression

# Wisconsin Physician Service Medicare Policy for Nivolumab in NSCLC

**(as of August 12, 2015 )**

Nivolumab Covered for squamous and nonsquamous  metatstatic NSCLC with progression on or after platinum-based chemotherapy (Aug. 1 Newsletter)

# Immuno-Oncology: Coverage Related Issues

- Payer ability to keep up with accelerating data-based new indications (e.g., new lines of therapy, new tumor types)
- Soon, there will be increasing utilization of anti-pd1s in combination with a host of agents (e.g., chemo, targeted, immunotherapeutic)
- As number of marketed anti-pd1s and anti-pdl1s increases will step therapy specifications be embedded into precert criteria to specify preferred agents
- Will coverage policy increasingly be biomarker driven (e.g., PDL1 overexpression)

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# Pembrolizumab

- Over 30 requests to date
  - No write-offs
- Utilize Merck support program for all patients
  - 0 received replacement assistance from Merck
  - 2 patients received copay assistance
- Indications
  - Metastatic melanoma (90%)
  - Lung
  - Cholangiocarcinoma
  - Renal cell

# Nivolumab

- Over 120 requests to date
  - No write-offs
- Utilize BMS support program for all patients
  - 19 patients received replacement assistance from BMS
  - 8 patients received copay assistance
    - BMS copay support and disease based grants
- Indications:
    - Metastatic Melonoma (42%)
    - Renal Cell (22%)
    - Lung (20%)
    - Squamous Cell Carcinoma (skin)
    - Non-Hodgkins Lymphoma
    - Bladder
    - Prostate
    - Merkel Cell

# The Merck Access Program Enrollment Form

Phone: 855-257-3932, Fax: 855-755-0518
The Merck Access Program
PO Box 29067
Phoenix, AZ 85038

**TO GET STARTED, COMPLETE THE ENROLLMENT FORM AND FAX TO 855-755-0518.**

Product name:_____

| ✔ | PLEASE CHECK ALL BOXES THAT APPLY AND COMPLETE THE APPROPRIATE SECTION(S) OF THE FORM | |
|---|---|---|
| ☐ | Patient Benefit Investigation | Section 1 |
| ☐ | Prior Authorization | Section 1 |
| ☐ | Appeal | Section 1 |
| ☐ | Merck Co-Pay Assistance Program | Sections 1, 2, 3 |
| ☐ | Referral to the Merck Patient Assistance Program[a] (offered through the Merck Patient Assistance Program, Inc.) | Sections 1, 2, 4 |

[a]Product replacement, available from the Merck Patient Assistance Program, may be available to health care providers whose patients do not have insurance or whose insurance does not cover the product, subject to certain financial, medical, and insurance criteria. The Patient Assistance Product Replacement Form may need to be submitted. Please call The Merck Access Program for additional information.

SECTION 1 *CONTINUED*

## HEALTH CARE PROVIDER INFORMATION (to be completed by health care provider)

Physician name:_____

Physician tax ID no.:_____ Physician NPI no.:_____ Physician license no.:_____

Address:_____

(Please provide a street address only, no PO boxes.)

City/State/Zip:_____

Phone:_____ Fax:_____

Office contact person:_____ Office contact number:_____

Practice/Facility name:_____

Practice tax ID no.:_____ Practice NPI no.:_____

Practice/Facility address:_____

City/State/Zip:_____

Please list all applicable ICD-9 codes:_____

Please list previous treatments:_____

Is patient BRAF V600 mutation positive? (Y/N):_____

## HEALTH CARE PROVIDER SIGNATURE AND DECLARATION (to be completed by health care provider)

**MUST CONTAIN ORIGINAL SIGNATURE**

By signing below, I represent and warrant the following:

- This request has been prepared exclusively by the physician or physician office identified in this request ("my Practice").
- My Practice has obtained written authorization from the patient identified in this request to disclose the patient's personal health information (PHI), including information relating to the patient's medical condition and prescription medications and the information disclosed in this patient enrollment form, as well as the information included in this request, to The Merck Access Program, sponsored by Merck Sharp & Dohme Corp. ("Merck"), a subsidiary of Merck & Co., Inc., or the Merck Patient Assistance Program ("PAP"), sponsored by the Merck Patient Assistance Program, Inc. (individually, "a Program"; collectively, "the Programs"), the administrators of the Programs, McKesson Specialty Arizona, Inc. ("McKesson") for The Merck Access Program and RxCrossroads for the Merck PAP, including their contractors or other affiliates, including, for McKesson, Covance Market Access ("Covance"), and for the Programs to use and disclose the information for the purposes of benefits investigation and reimbursement support.
- My Practice has provided the patient identified in this request with the notices necessary to comply with all federal and state laws and regulations relating to medical and/or health privacy, including, but not limited to, the HIPAA Privacy Rule, codified at 45 C.F.R. Parts 160 and 164, as amended from time to time.
- I certify that I, or a physician in my Practice, have determined that the prescribed product is medically appropriate for the patient identified above and that I, or a physician in my Practice, will be supervising the patient's treatment.
- If the patient receives product through the Merck PAP, reimbursement for such product administered to the patient will not be sought from any source.
- I also understand that neither I nor my Practice will receive any reimbursement from Merck, whether for administration fees or otherwise.
- I understand that information concerning program participants may be summarized for statistical or other purposes and provided to Merck and/or the Programs.
- I verify that the information provided is complete and accurate to the best of my knowledge.

Physician's original signature:_____ Date:_____

Physician's name (please print):_____ License no.:_____

Is physician licensed in Vermont? (Y/N):_____ If yes, provide Vermont license no.:_____

**The Merck Access Program**

PO Box 29067
Phoenix, AZ 85038

Phone: 855-257-3932
Fax: 855-755-0518

Patient Initials: _____ MAP Case number: _____

***Due to the diagnosis and/or absence of prior treatments submitted on the MAP enrollment form, please have the physician select and sign ONE certification to indicate how KEYTRUDA is being prescribed:***

☐ **NCCN Certification**

***I certify that I, or a physician in my Practice, have prescribed KEYTRUDA consistent with the NCCN levels of evidence for Category 1 or Category 2A. The NCCN guidelines are located at www.nccn.org.***

***Please note: If KEYTRUDA is being prescribed for a non-FDA approved indication, your patient is not eligible for the Merck Co-pay Assistance Program, nor is your patient eligible for you to receive product replacement through the Merck Patient Assistance Program.***

***Physician Signature*** _____ ***Date*** _____

☐ ***Unapproved Use Certification***

***(Not contained in NCCN Guidelines)***

***Please read the FDA-approved label for KEYTRUDA before prescribing. If the indication for which you are prescribing KEYTRUDA is not listed in the label, you are prescribing the medication for an "unapproved" use. The fact that the use for which you are prescribing this medication is not listed in the FDA-approved label indicates that the FDA has not approved the efficacy, dosage amount, or safety of this medication when used for such a use.***

***By signing below, I certify that (1) the above therapy is medically appropriate; and (2) clinical trials were not a viable option for this patient. For information about currently enrolling clinical trials, please call the Merck National Service Center at 800-672-6372 or visit www.clinicaltrials.gov.***

***Please note: If KEYTRUDA is being prescribed for a non-FDA approved indication, your patient is not eligible for the Merck Co-pay Assistance Program, nor is your patient eligible for you to receive product replacement through the Merck Patient Assistance Program.***

***Physician Signature*** _____ ***Date*** _____

Bristol-Myers Squibb
access|support®
YOUR PATIENT. OUR COMMITMENT.

**Oncology Reimbursement Support**
Phone: 1-800-861-0048 Fax: 1-888-776-2370
P.O. Box 221509
Charlotte, NC 28222-1509

## Selection of Services (to be completed by provider)

☑ Benefit Investigation / Prior Authorization / Appeals Assistance

**Access to Care Services** *Please choose all services you would like to use.*

☑ BMS Oncology Co-Pay Program (program available for Ixempra, Opdivo, and Yervoy)
*Please read and sign the Co-Pay agreement. Applying for Co-Pay assistance does not guarantee receipt of acceptance into the program.*

☑ Comprehensive Coverage Research
*Research provides assistance to my patient in the nature of researching alternative methods of coverage of a BMS product*

☐ Specialty Pharmacy Services (for Oral Medications Only)
Preferred Specialty Pharmacy: _____

☑ Screening for Bristol-Myers Squibb Patient Assistance Foundation (BMSPAF)

## Product Prescribed (to be completed by provider)

☐ DROXIA® (hydroxyurea)
☐ ERBITUX® (cetuximab)
☐ ETOPOPHOS® (etoposide phosphate)
☐ IXEMPRA® (ixabepilone)
☐ LYSODREN® (mitotane)
☑ OPDIVO® (nivolumab)
☐ SPRYCEL® (dasatinib)
☐ YERVOY® (ipilimumab)

## Treatment Information (to be completed by provider)

Patient Name _____
First Middle Initial Last

Patient Diagnosis: ICD-9 or ICD-10 Code _____ Description _____

Will this be? ☐ Monotherapy ☐ In Combination With _____

Therapy Provided in: ☐ Doctor's Office ☐ Hospital ☐ Outpatient Facility

Is Doctor Contracted with Patient's Insurance? ☐ Yes ☐ No

| Therapy GIVEN | | | Therapy PLANNED | | |
|---|---|---|---|---|---|
| Dates | Dose | Frequency | Dates | Dose | Frequency |
| | | | | | |
| | | | | | |

**Erbitux-related testing:**

*KRAS* Tested? ☐ Yes ☐ No If "Yes", what was the result? _____

EGFR Tested? ☐ Yes ☐ No If "Yes", what was the result? _____

## Patient Information (to be completed by patient)

### Personal Information

Name _____ Date of Birth ___/___/___
First Middle Initial Last

Address _____

City _____ State _____ Zip _____

Home Phone (___) _____ Cell Phone (___) _____

Patient E-mail Address _____

Social Security Number* _____ Gender: ☐ Female ☐ Male

*Providing Social Security Number is optional.

Allergies _____

Medications currently taking _____

### Financial Information (complete if choosing Comprehensive Coverage Research or BMSPAF)

Number of people in your household _____ (Include yourself, your spouse and your dependents) Total household income: $_____ per month OR $_____ per year

Your application may be subject to audit or request for additional documentation.

### Insurance Information

Do you have insurance through: (please check all that apply)

☐ Private Insurance ☐ VA or Military ☐ State Assistance program for medication ☐ Medicaid

Medicare: ☐ Part A ☐ Part B ☐ Part D ☐ Medicare Advantage ☐ None

| Insurance Name | Phone | ID/Policy # | Group# | Policy Holder |
|---|---|---|---|---|
| *Primary Insurance: Please list below* | | | | |
| | | | | |
| *Secondary Insurance: Please list below* | | | | |
| | | | | |
| *State, Veteran or other Prescription Coverage: Please list below* | | | | |
| | | | | |

*If you chose Medicaid or Veteran status above, please choose applicable options below.*

**Medicaid Status** ☐ Not Applied ☐ Denied ☐ Application Pending

**Veteran Status** ☐ Yes ☐ No Applied for VA ☐ Yes ☐ No

Please continue to the pages 4-5 to read and sign the Patient Authorization and Agreement.

# Support Program Experience

- We use the support programs whether on or off-label for both medications
- On-label requests follow our High Dollar Medication Process flow algorithm
- Off-label requests follow either the Medicare or Other Payers Process flow algorithms

# Payer Experience

- Medicare
  - No LCD yet
  - Require signed ABN if off label
- Managed Medicare
  - Clinical policy guidelines are available for all major payer plans
  - Require off-label predetermination
    - Off-label considered with clinical support and patient information, decisions on a case-by-case basis
  - Require NONC with unsuccessful predetermination

# Payer Experience

- Medicaid
  - Can not require NONC
  - If denied, only option is a support program
- Managed Medicaid
  - Clinical policy guidelines are available (Caresource, Molina, etc.)
  - Require off-label predetermination
    - Off-label considered with clinical support and patient information, decisions on a case-by-case basis
  - Require signed NONC with unsuccessful predetermination

# Payer Experience

- Anthem, Humana, Aetna, Cigna
  - Clinical policy guidelines are available for all
  - Require off-label predetermination
    - Off-label considered with clinical support and patient information, decisions on a case-by-case basis
  - Require signed NONC with unsuccessful predetermination
  - Anthem appears to have most scrutiny and where we have seen the most denials even after pre-determination authorization

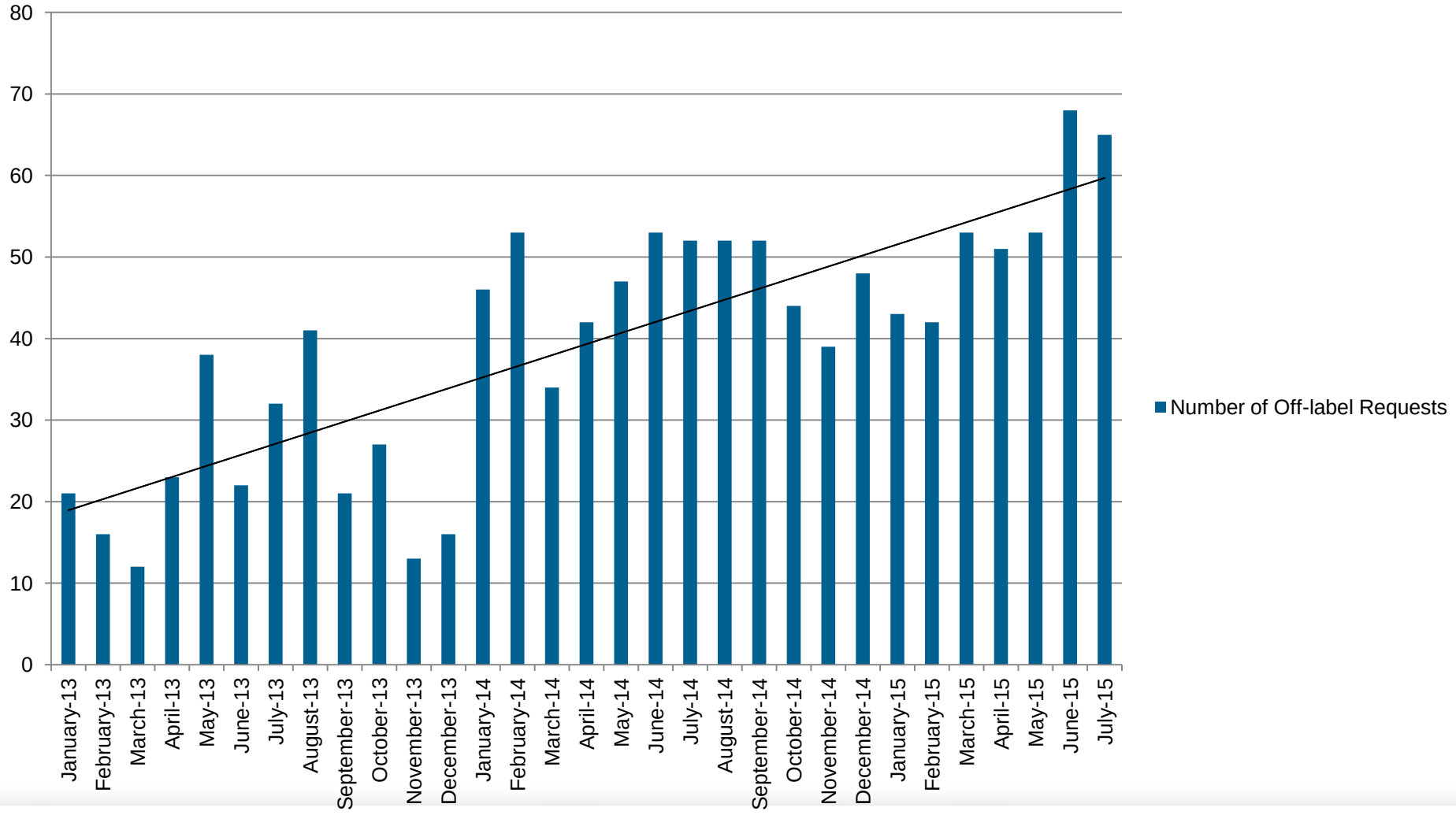
# Payer Experience

- United Health Care
  - Follows NCCN Guidelines
  - Require off-label predetermination
    - Off-label considered with clinical support and patient information, decisions on a case-by-case basis
  - Require signed NONC with unsuccessful predetermination
- *Patients willing to pay out-of-pocket, if necessary for entire therapy*

# Challenges

- Requests for off-label use immediately following FDA approval
- Payers initially not prepared to answer coverage questions and render decisions
- Support programs are different
  - Testing requirement
  - Off-label support
- Resource intense
  - Clinical team (physicians, pharmacists, APPs)
  - Reimbursement staff

# Number of Off-Label Requests



# Challenges

- Communication/coordination due to multiple individuals and processes involved (internal/external)
- Out of pocket payments
- Budget impact
  - Current off-label use
  - Pending indications
  - Number of clinical trials

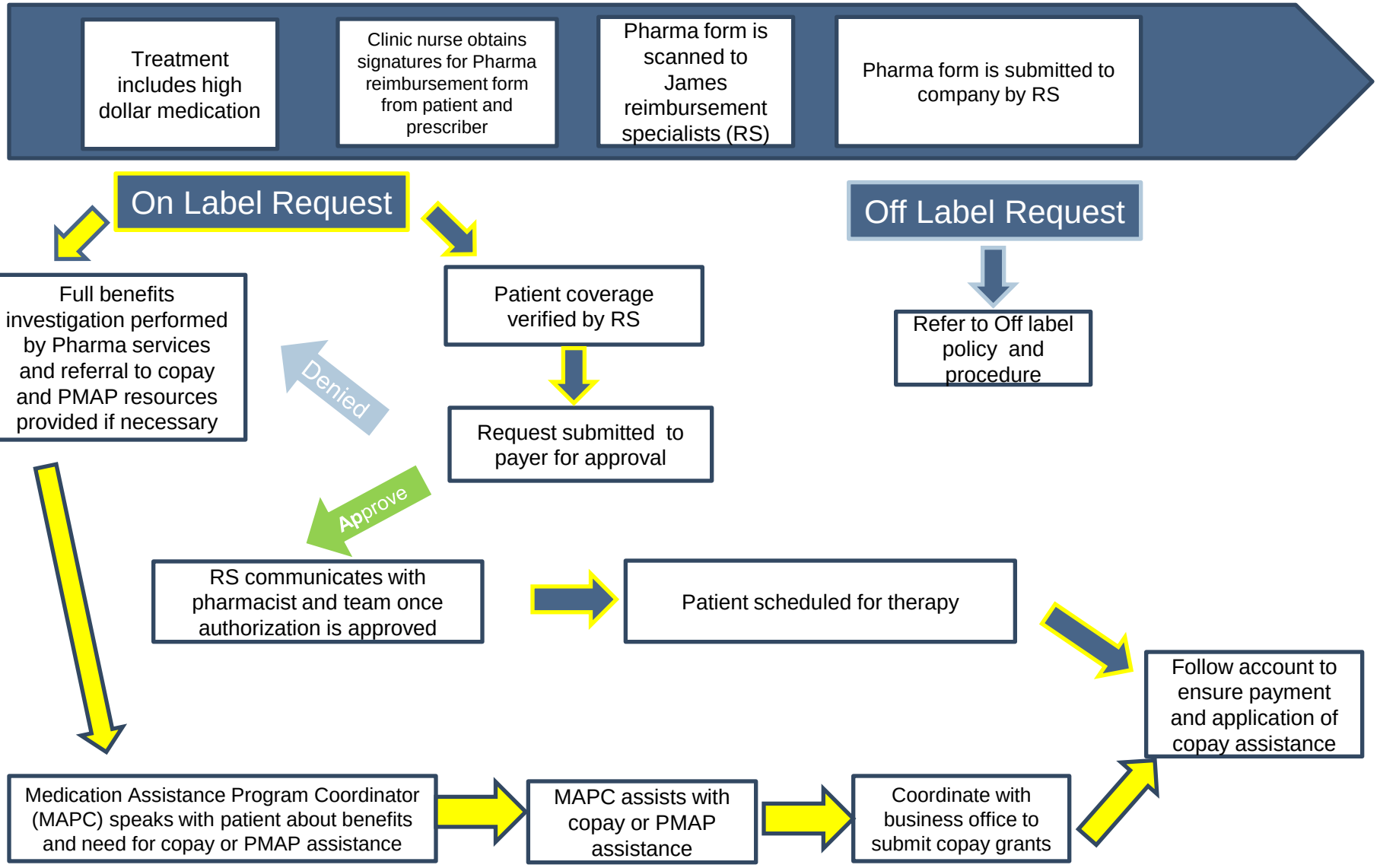
# How have we made it work?

- High dollar medication approval process
  - Enroll every patient into a support program, regardless of on or off-label
  - Clinical specialist pharmacist at point of care provides support and engages clinical team
- Robust 0ff-Label Policy and Procedure
  - All off-label requests require predetermination
  - Patients are made aware of risks and benefits, including financial risk
  - Patients are required to sign an ABN or NONC
  - Utilize peer review process as necessary

# How have we made it work?

- Added Reimbursement Specialists to the Pharmacy Department
  - Handle all high dollar approvals
    - Submit manufacturer program application and perform precertification
  - Handle all off-label predeterminations
  - Engage directly with Clinical Specialist Pharmacists
  - Determine out of pocket payment amount when necessary
- Pharmacy follows every claim to ensure payment
- Developed detailed process flows

# High Dollar Process



# Predetermination Process

- Formal process with a team approach
- Key players:
  - Pharmacist
  - Physician
  - Advanced Practice Provider (CNP or PA)
  - Reimbursement Specialist
- Effective and traceable form of communication is essential

# Predetermination Process

- Pharmacist role
  - Discuss rationale for off-label use with the team
  - Retrieve supporting literature
  - Review CMS approved compendia and NCD/LCD
  - Enter request into off-label use database
    - Entry triggers an email to pharmacy director, P&T committee chair, reimbursement specialist team

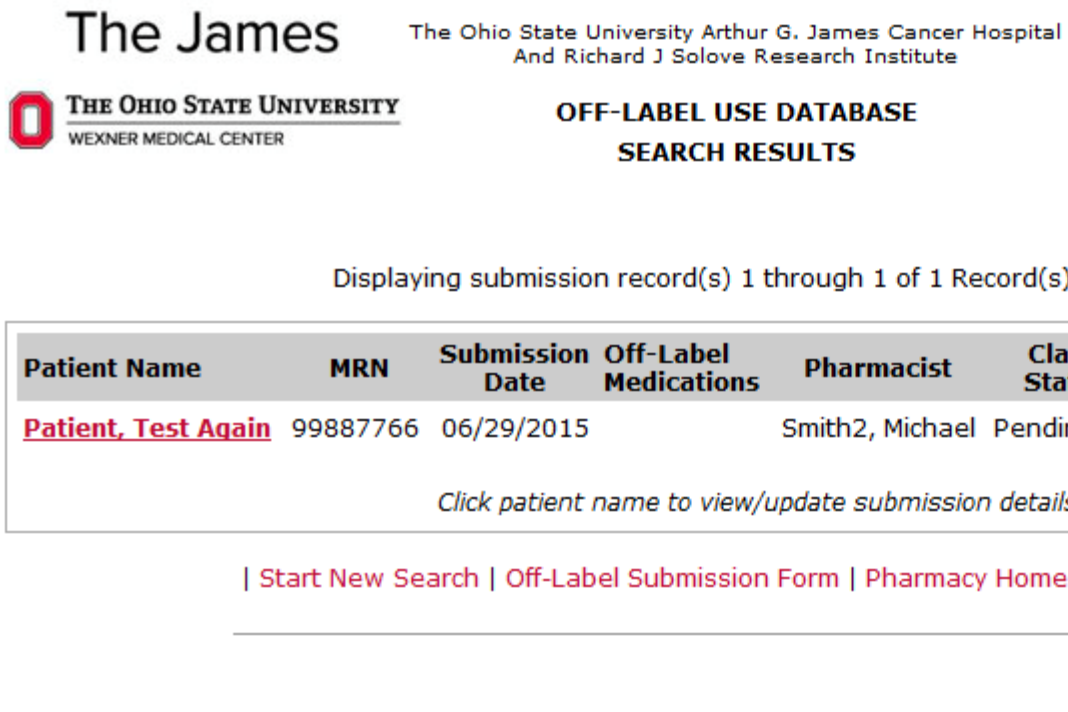
# Predetermination Process

- Reimbursement Specialist role
  - Verify medical insurance
  - Obtain copies of pertinent information from patient medical record (treatment plan, diagnostic studies, etc.)
  - Retrieve supporting literature (if not already provided by team)
  - Verify compendia and NCD/LCD support
  - Identify appropriate ICD-9 code(s) and HCPCS code(s) for medications

# Predetermination Process

- Reimbursement Specialist role
  - 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

# James Off Label Database



The James

The Ohio State University Arthur G. James Cancer Hospital
And Richard J Solove Research Institute

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

**OFF-LABEL USE DATABASE**
**SEARCH RESULTS**

Displaying submission record(s) 1 through 1 of 1 Record(s) Found

| Patient Name | MRN | Submission Date | Off-Label Medications | Pharmacist | Claim Status | Payor | Submission Status |
|---|---|---|---|---|---|---|---|
| Patient, Test Again | 99887766 | 06/29/2015 | | Smith2, Michael | Pending PC | Other Payors | Open |

*Click patient name to view/update submission details*

| Start New Search | Off-Label Submission Form | Pharmacy Home | OneSource |

[ Logout ]

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**OFF-LABEL USE DATABASE**
**SUBMISSION SEARCH FORM**

***Select Search Criteria***

*Select multiple criteria to narrow results*

**Patient Last Name:**

**Patient MRN:**

**Pharmacist:**

**Date range:**

Beginning date: (m/d/yyyy)

Ending date: (m/d/yyyy)

**Pre-Cert Status:**
- Pending Pre-D
- Pending Admin
- Admin Approved
- Pre-D Submitted
- Pre-D Approved
- Pre-D Denied
- Pre-D Appealed
- Cancelled

**Payor:** Medicaid Medicare Self-pay Other Payors

SEARCH Reset

| Start New Search | Off-Label Submission Form | Pharmacy Home | OneSource |

[ Logout ]

**Key:**
**Pending Pre-D** = waiting on reimbursement team
**Pending Admin** = Awaiting pharmacy administration review
**Admin Approval** = Administration approval
**Pre-D** = Pre-determination

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**OFF-LABEL USE DATABASE**
**RECORD DETAIL**

**Patient Name:** Patient, Test Again
**MRN:** 99887766
**Dx Code(s):** 1234
**Pharmacist:** Smith2, Michael
*Phone:* *Pager:*

**Submission Date:** 06/29/2015 **Rec ID:** 944
**Location:** 5-CCCT
**Diagnosis:** Sorry, This is another test submission. Please ignore. --Kim

| TREATMENT REGIMEN | | | | | |
|---|---|---|---|---|---|
| **Regimen Details** *( please indicate treatment frequency/days, cycle length, etc)* | | | | | |
| Another test submission | | | | | |
| **Medication** | **Dose** (ex: mg/m$^2$) | **Patient's Calculated Dose** | **ACQ Cost Per Dose** | **No. Doses Per Cycle** | **Use Off-Label** |
| 1. | | | | | |
| 2. | | | | | |
| 3. | | | | | |
| 4. | | | | | |

**Planned cycles per regimen:** 0
**Cost per treatment cycle:** $
**TOTAL treatment cost:** $0
**Physician:** Awan, Farrukh
**Disease Service:** GI Med/Onc
**Reason for Off-Label Use:**
Another test submission

| PEER REVIEW SUPPORT | | | |
|---|---|---|---|
| **Medication 1** | **Medication 2** | **Medication 3** | **Medication 4** |
| ☐ FDA Approved | ☐ FDA Approved | ☐ FDA Approved | ☐ FDA Approved |
| ☐ NCD-covered indication | ☐ NCD-covered indication | ☐ NCD-covered indication | ☐ NCD-covered indication |
| ☐ LCD-covered indication | ☐ LCD-covered indication | ☐ LCD-covered indication | ☐ LCD-covered indication |
| ☐ AHFS-DI-Indication is supportive | ☐ AHFS-DI-Indication is supportive | ☐ AHFS-DI-Indication is supportive | ☐ AHFS-DI-Indication is supportive |
| ☐ NCCN-Indication is Category 1 or 2A | ☐ NCCN-Indication is Category 1 or 2A | ☐ NCCN-Indication is Category 1 or 2A | ☐ NCCN-Indication is Category 1 or 2A |
| ☐ DrugDex-Indication is Class I, IIa, or IIb | ☐ DrugDex-Indication is Class I, IIa, or IIb | ☐ DrugDex-Indication is Class I, IIa, or IIb | ☐ DrugDex-Indication is Class I, IIa, or IIb |
| ☐ Two Phase II Studies | ☐ Two Phase II Studies | ☐ Two Phase II Studies | ☐ Two Phase II Studies |
| ☐ One Phase III Study | ☐ One Phase III Study | ☐ One Phase III Study | ☐ One Phase III Study |
| ☐ Other | ☐ Other | ☐ Other | ☐ Other |
| ☐ None Available | ☐ None Available | ☐ None Available | ☐ None Available |
| If Other checked, please describe: | If Other checked, please describe: | If Other checked, please describe: | If Other checked, please describe: |

**MRN:** Medical Record Number
**Dx Code**: diagnosis code

| CLAIM DETAILS | |
|---|---|
| **Claim status:**<br>○ Patient receiving medication<br>◉ Pending payment<br>○ Denied-pending appeal<br>○ Appealed<br>○ Denied-final<br>○ Completed-paid<br>○ Not given | |
| **Service Date(s):** 07/12/15, 07/19/15 | |
| **HAR(s):** 07/01/2015, 07/07/2015 | |
| **Total Amount Reimbursed:** $20,345.00 | |
| **Bundled or Inpatient:** ○ Yes ◉ No | |
| **Reason if claim denied:** ○ Medical necessity ○ No authorization ○ Experimental/investigational ◉ Other | |
| **If "other", please describe:** other denied reason test- appeal submitted reference# 123456856 | |
| **Total acquistion Cost of Denied Drug(s):** $500.00 | |
| **Total amount recovered by appeal:** $500.86 | |
| **Total amount replaced by manufacturer:** $0.12 | |
| **Claim comments:** claim comments go here | |
| | |
| **Last modification date:** 07/27/2015 | **Last modified by:** S Hudson-DiSalle |

UPDATE RECORD

## CLAIM DETAILS

**Claim status:**

- ○ Patient receiving medication
- ◉ Pending payment
- ○ Denied-pending appeal
- ○ Appealed
- ○ Denied-final
- ○ Completed-paid
- ○ Not given

**Service Date(s):** 07/12/15, 07/19/15

**HAR(s):** 07/01/2015, 07/07/2015

**Total Amount Reimbursed:** $20,345.00

**Bundled or Inpatient:** ○ Yes ◉ No

**Reason if claim denied:** ○ Medical necessity ○ No authorization ○ Experimental/investigational ◉ Other

**If "other", please describe:** other denied reason test- appeal submitted reference# 123456856

**Total acquistion Cost of Denied Drug(s):** $500.00

**Total amount recovered by appeal:** $500.86

**Total amount replaced by manufacturer:** $0.12

**Claim comments:** claim comments go here

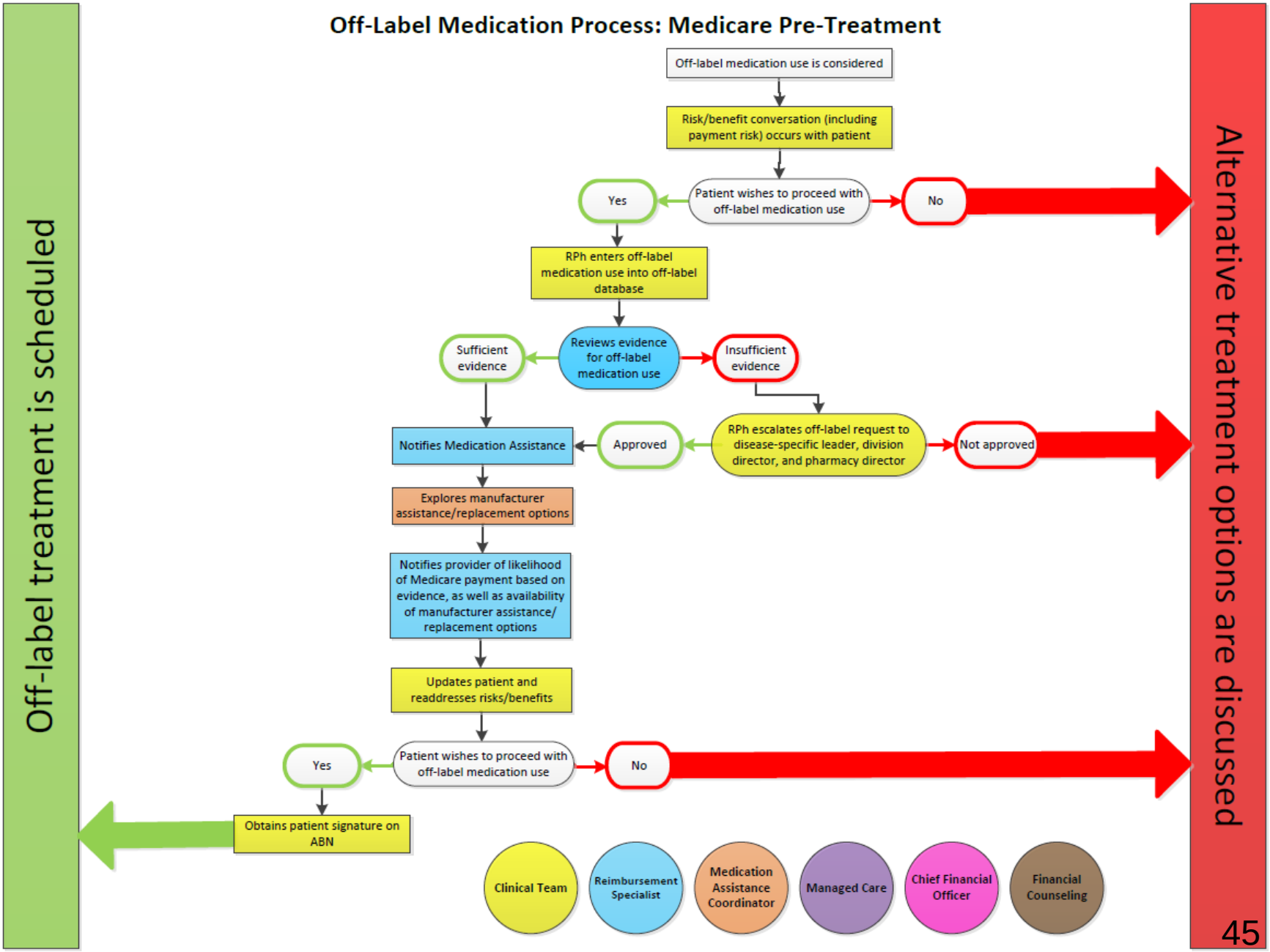
| | |
|---|---|
| **Last modification date:** 07/27/2015 | **Last modified by:** S Hudson-DiSalle |

UPDATE RECORD

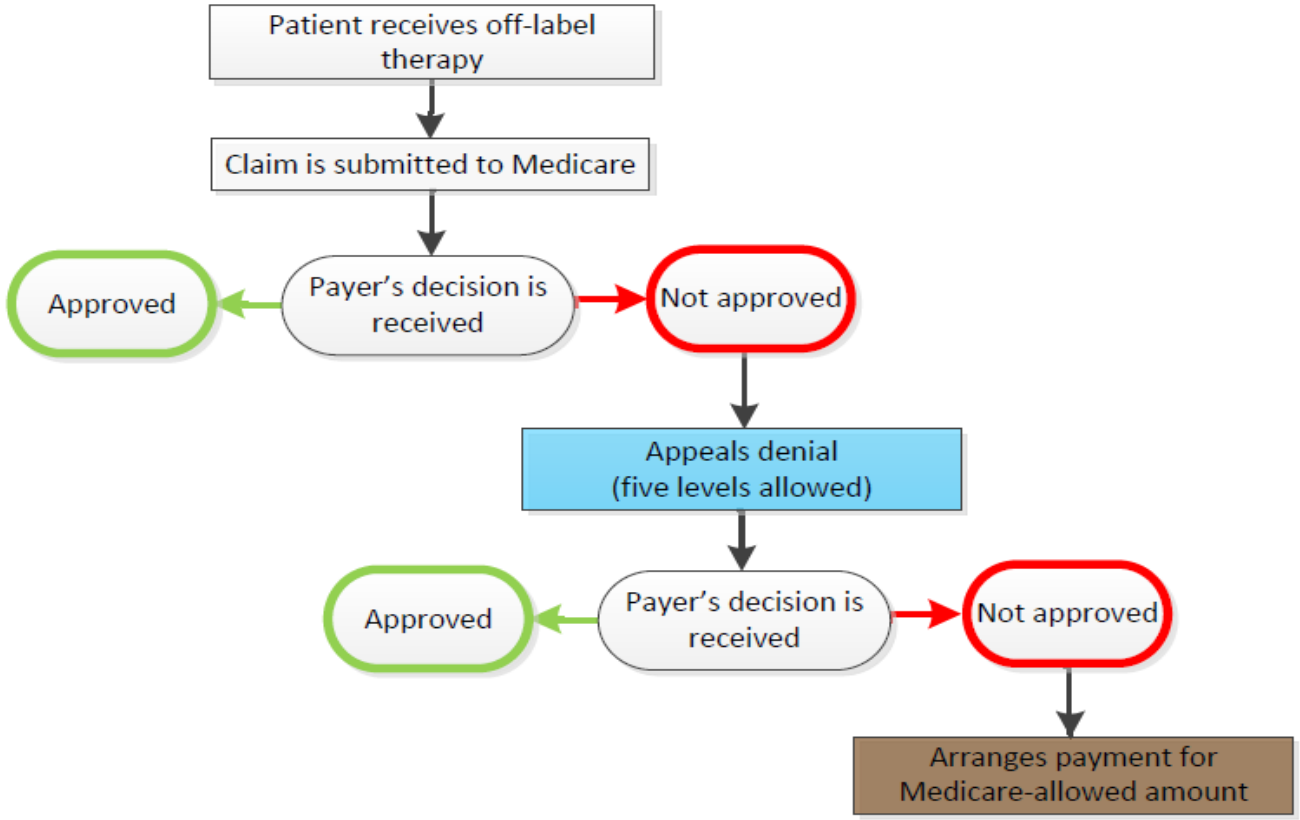
# Peer Review Process

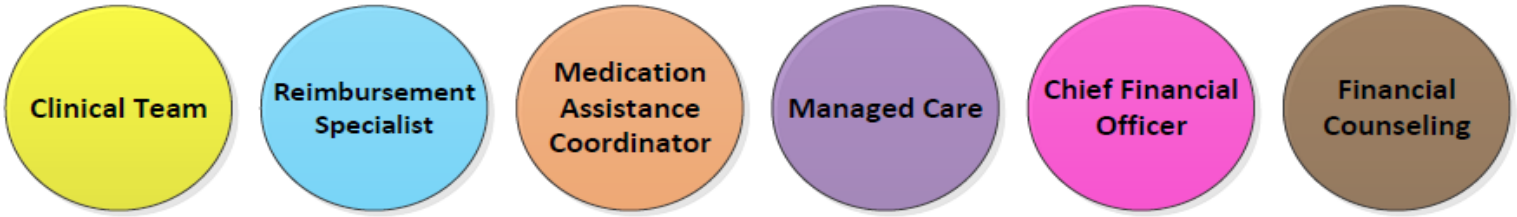
- Off-label requests lacking supportive evidence require approval by:
  - Disease Specific Leader (GI, GU, Lung, etc..)
  - Division Director (hematology or oncology)
  - Pharmacy Administrator/Director
- Safety, efficacy, and cost must be considered
- Decisions may take up to 72 hours depending on availability of individuals

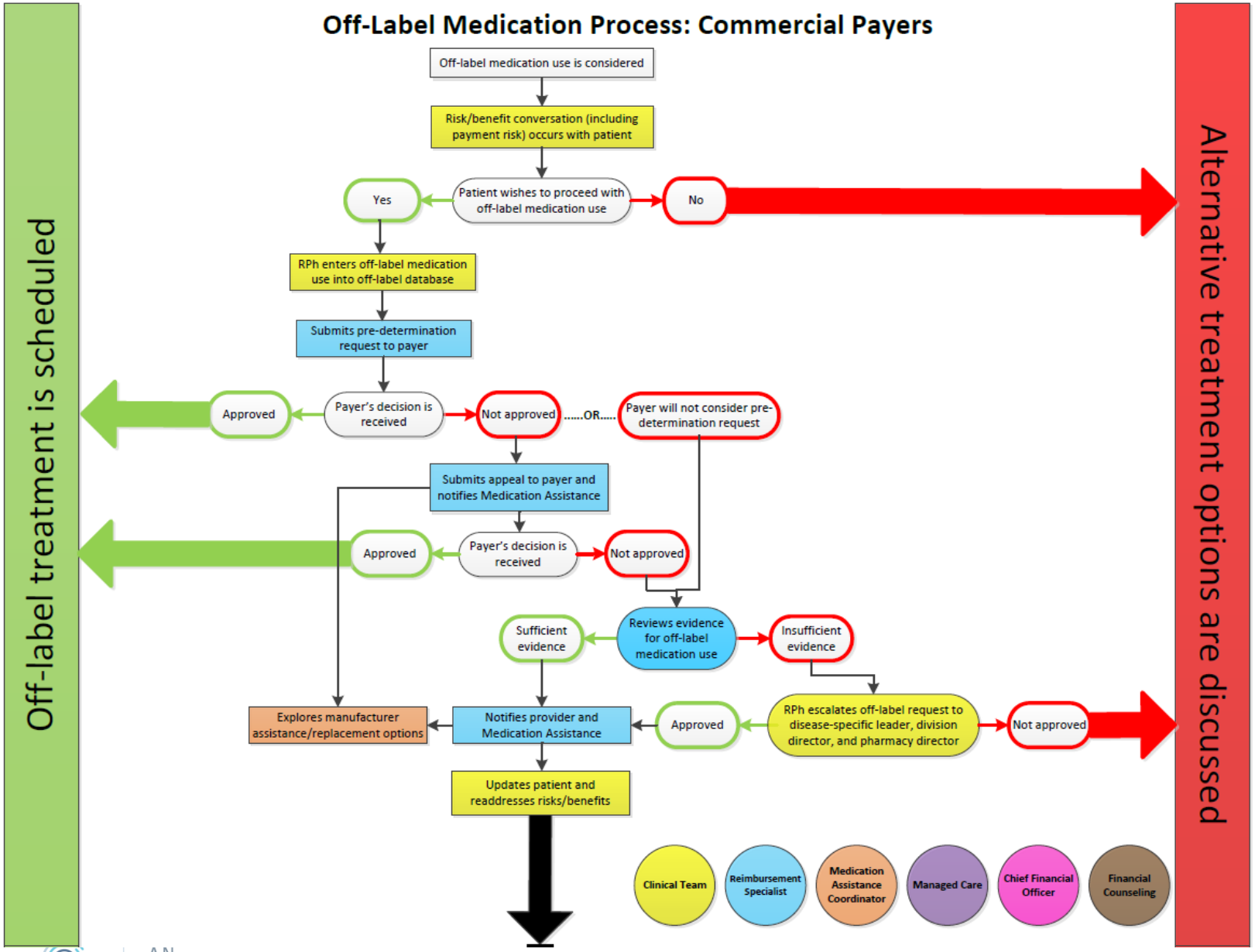
# Off-Label Medication Process: Medicare Pre-Treatment



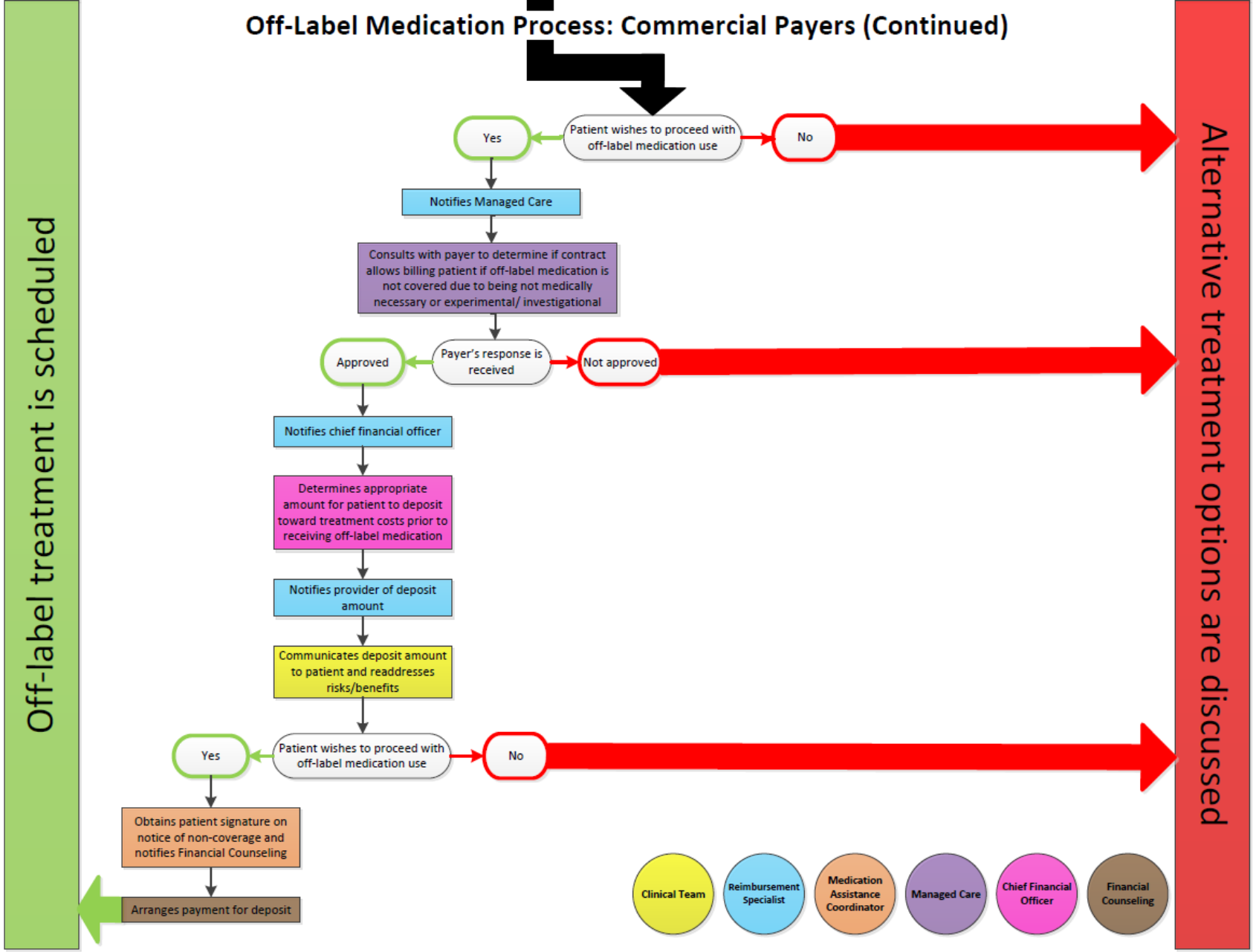
# Off-Label Medication Process: Medicare Post-Treatment




Off-Label Medication Process: Commercial Payers
Off-label treatment is scheduled
Alternative treatment options are discussed
Off-label medication use is considered
Risk/benefit conversation (including payment risk) occurs with patient
Patient wishes to proceed with off-label medication use
Yes
No
RPh enters off-label medication use into off-label database
Submits pre-determination request to payer
Payer's decision is received
Approved
Not approved
.....OR.....
Payer will not consider pre-determination request
Submits appeal to payer and notifies Medication Assistance
Payer's decision is received
Approved
Not approved
Reviews evidence for off-label medication use
Sufficient evidence
Insufficient evidence
RPh escalates off-label request to disease-specific leader, division director, and pharmacy director
Approved
Not approved
Notifies provider and Medication Assistance
Explores manufacturer assistance/replacement options
Updates patient and readdresses risks/benefits
Clinical Team
Reimbursement Specialist
Medication Assistance Coordinator
Managed Care
Chief Financial Officer
Financial Counseling

# Off-Label Medication Process: Commercial Payers (Continued)



# Questions?

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