Positioning Your Program to Tackle Immuno-Oncology Integration Challenges

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The James Cancer Hospital and Solove Research Institute at The Ohio State University

ICLIO 1st Annual National Conference

10.2.15

Philadelphia, Pa.

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AN INSTITUTE OF ACCC Association of Community Cancer Centers

Financial Disclosures

- I currently have or have the following relevant financial relations to disclose:
  - Advisory Board: Amgen, Bristol-Myers Squibb, Eagle, Genentech, Lilly, Merck, Seattle Genetics, Spectrum, Sunesis, Teva

Off-Label Use Disclosures

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

Overview

- Key Administrative Challenges
- Strategies for Success
- Present Coverage for I-O agents
- Practice Considerations and Needs for Coverage and Reimbursement
- Internal Demand for Use of I-O agents
- Reimbursement Concerns
- Implementing Best Practices and Preparing Your Practice for Success

Key Administrative Challenges

1. Managing onslaught of new information for staff and patients, and ensuring that all are appropriately educated

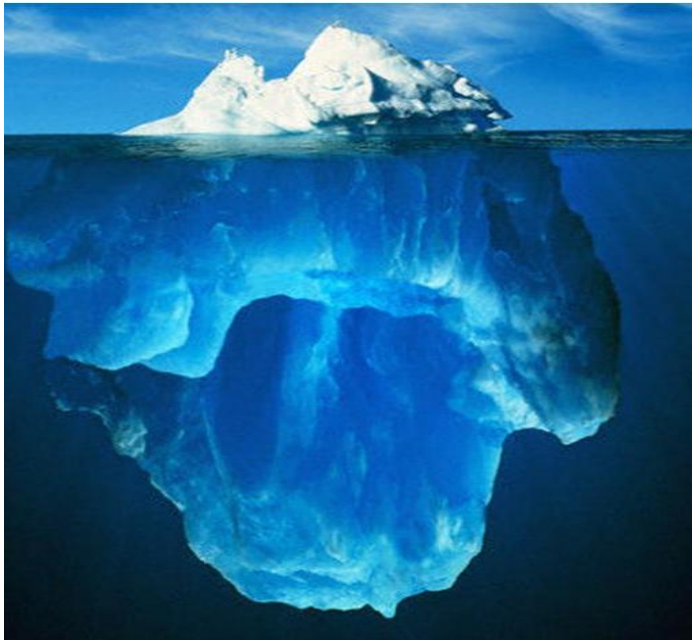
2. Ensuring patients are triaged appropriately, particularly with regard to new or unfamiliar adverse events

3. Managing reimbursement, patient financial support, and cash flow implications of new products

[1]

Managing onslaught of new information for staff and patients, and ensuring that all are appropriately educated

Keeping Up With New Information



- Current products on the market are the “tip of the iceberg” when looking at manufacturers’ I-O pipelines
- During the next one to five years, we can expect a new I-O product every few months
- Not only new products, but a myriad of new combinations and regimens

How can practices and their staffs keep up with the new information, stay informed, and make sure patients are appropriately educated?

Strategies for Information Management and Education

1. Identify an “Immuno-Oncology Champion” from among your providers to be the “I-O point person” responsible for all product questions and staff education
2. Identify a core group within your practice to manage patient education, including the review of existing patient materials and/or the development of new materials specific to I-O agents and management of their adverse effects
3. Proactively update staff on new information and consider use of manufacturer-provided resources including on-site training/education

[2]

Ensuring patients are triaged appropriately, particularly with regard to new or unfamiliar adverse events

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Triage of Patients With Adverse Events

- I-O agents have an adverse event profile that differs from those associated with chemotherapy or commonly used biologic agents
- Staff triaging patient phone calls need to be aware of potentially serious adverse events requiring immediate attention
    - Example: If patients go to ED or other setting, hospital clinicians need to be made aware of adverse events associated with I-O therapies
- Educating patients/staff and developing protocols for patient triage/management will help ensure that adverse events are quickly identified, managed, and mitigated

Have you updated your practice protocols, particularly with regards to triaging patients, to account for patients on I-O therapies and the associated potential for adverse events?

Strategies for Triage of Patients With Adverse Events

1. Use your “I-O Champion” to take the lead in developing/revising any treatment protocols that may be impacted by the addition of new I-O therapies in your practice

2. Educate all patients on an I-O therapy to clearly identify themselves as on a I-O therapy. Make sure that these patients can be quickly identified as being on an I-O therapy in their medical record

3. As part of staff education, ensure that clinical and non-clinical staff understand and can identify the most common adverse events associated with I-O products, and know when these events could be potentially life-threatening and/or require immediate clinical attention

[3]

Managing reimbursement, patient financial support, and cash flow implications of new products.

Managing Reimbursement and Finances

- New to market I-O agents may not have specific J-Code assigned
- The high demand for off-label use of new products leads to reimbursement questions/concerns
- Private payers have been reported to be sending retrospective denials, particularly for off-label uses, **even when there was a pre-determination in acceptance of the use**.

How can practices ensure financial stability and viability while quickly making new I-O therapies available to patients? How can practices best ensure that they are reimbursed, and that patients have the financial support that they need?

Strategies for Reimbursement and Financial Management

1. Ensure process is in place for appropriate management/billing until J-Code is assigned

2. Identify a point person from within your financial or reimbursement staff to focus on I-O agents and understand the nuances of the various manufacturer programs, co-pay foundations, and patient assistance programs to optimize reimbursement and patient support.

3. Ensure your practice has sufficient Patient Advocate support. Most practices have found that Financial Counselors/Medication Assistance Coordinators pay for themselves many times over; if you are not sure if you have enough, it's a good time to conduct an analysis.

Strategies for Reimbursement and Financial Management

4 Require precertification for all on-label uses and enroll all patients in manufacturer-sponsored program for benefits investigation/copay support

5 Develop an off-label policy for IO therapies. Suggested best practice:

- Require predetermination for all off-label requests
- Enroll all patients in manufacturer-sponsored program for benefits investigation, appeals, and potential medication replacement
- Ensure patients are made aware of risks and benefits, including financial
- Require patients to sign an Advanced Beneficiary Notice or Notice of Non-Coverage

6 Be prepared for patients who may be willing to pay for I-O therapies out of pocket**.** Patient advocates should be well versed in having that conversation with patients in addition to talking about their benefits and potential support program assistance

Current Coverage & Reimbursement Policies

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Aetna Coverage Policy for Nivolumab and Pembrolizumab (as of Sept 30, 2015)

- Nivolumab**

  Covered for incompletely resected or unresectable metastatic or recurrent melanoma

  Covered for NSCLC with progression on or after cytotoxic chemotherapy

  ***Requires preauthorization*

- Pembrolizumab

  Covered for incompletely resected or unresectable metastatic or recurrent melanoma

Anthem Coverage Policy for Nivolumab and Pembrolizumab (as of Sept 30, 2015)

- Nivolumab

  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 cytotoxic chemotherapy

- Pembrolizumab

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

Wisconsin Physicians Service Medicare Policy for Nivolumab in NSCLC (as of Sept 30, 2015)

Nivolumab covered for metastatic NSCLC with progression on or after platinum-based chemotherapy

Note: WPS covers pembrolizumab and covers nivolumab as monotherapies for the treatment of metastatic melanoma

The James Experience with Immuno-oncology Agents

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Pembrolizumab

- Twenty patients treated
  - No write-offs
  - One account being appealed, due to denial for rounding
- Utilize Merck support program for all patients
  - 0 received replacement assistance from Merck
  - 4 patients received copay assistance for an off-label indication that was covered by commercial payer
- Indications
  - Metastatic melanoma (90%)
  - Lung
  - Cholangiocarcinoma
  - Renal cell

Nivolumab

- 128 patients treated
  - No write-offs
- Utilize BMS support program for all patients
  - 47 patients received replacement assistance from BMS
  - 14 patients received copay assistance
    - BMS copay support and disease based grants
- Indications:

Renal Cell (28%)
Metastatic Melanoma (25%)
Lung (24%)
Squamous Cell Carcinoma (skin)
Non-Hodgkins Lymphoma
Bladder
Prostate
Head/Neck
Merkel Cell
Porocarcinoma

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 _____ (First / Middle Initial / Last) Date of Birth ___/___/___
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

Payer Experience

- Anthem
  - Melanoma pathway lists Nivolumab as the preferred agent
  - Appear to have most scrutiny and where we have seen the most denials even after pre-determination authorization

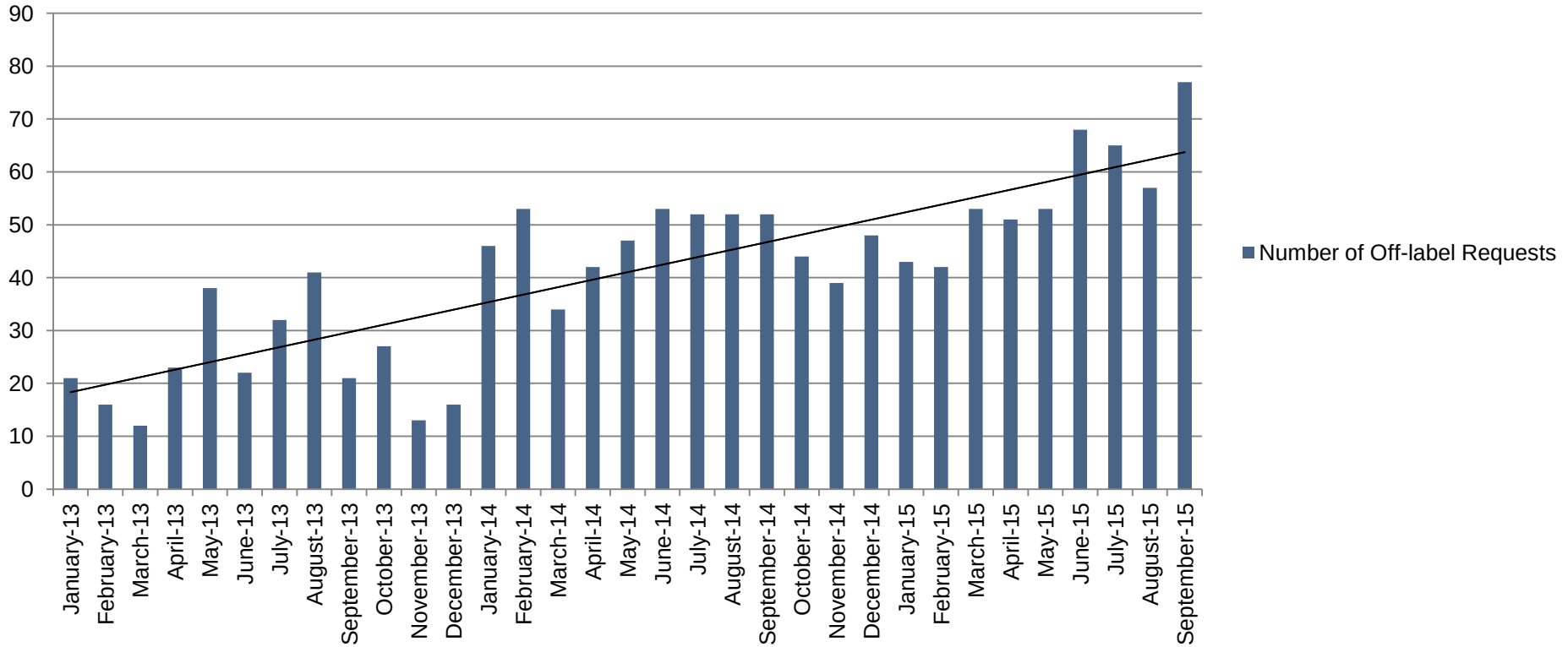
Payer Experience

- 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 (initially)
- 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

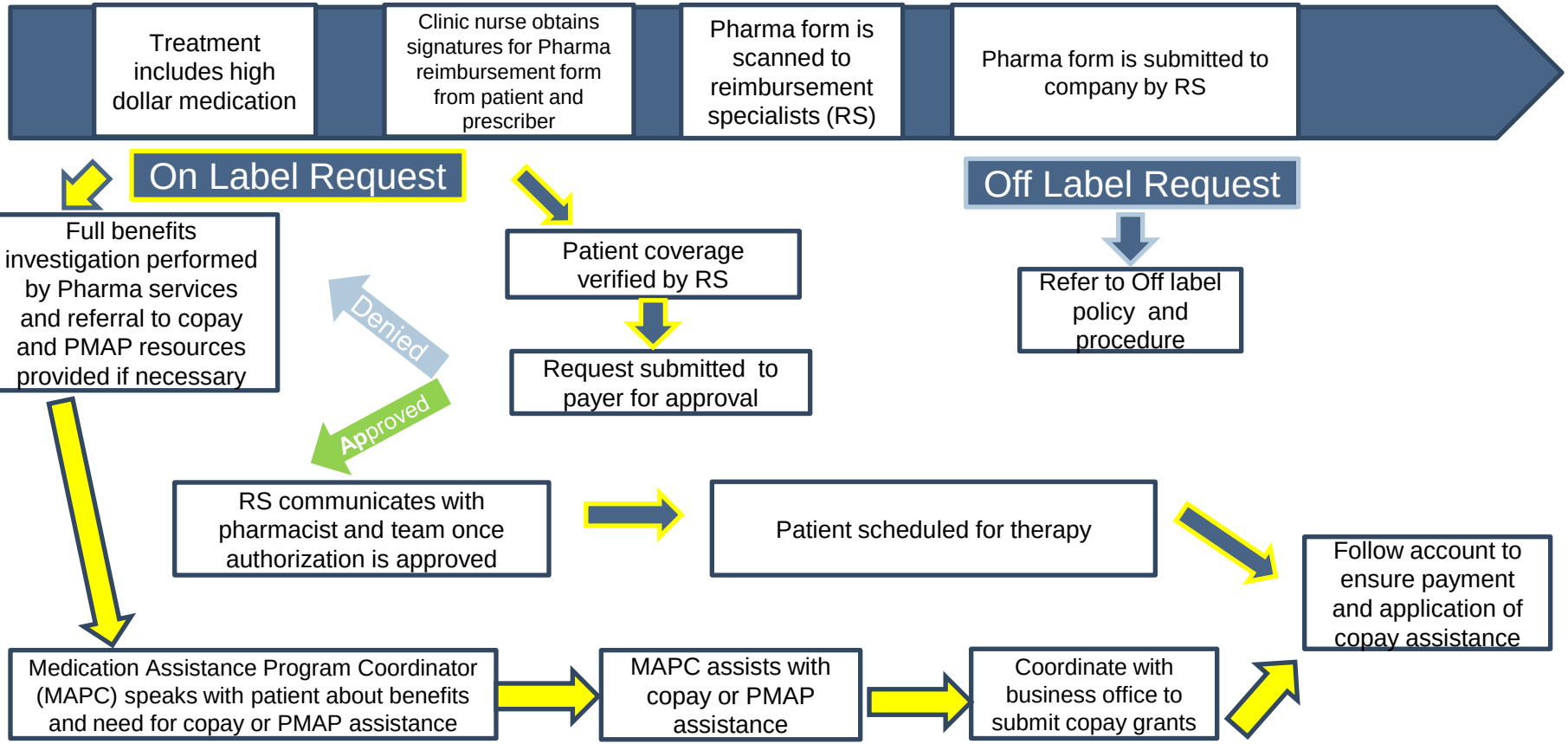
How have we made it work?

- 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
WEXNER MEDICAL CENTER

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

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]

The James

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WEXNER MEDICAL CENTER

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: $
Physician: Awan, Farrukh
Reason for Off-Label Use:
Another test submission

TOTAL treatment cost: $0
Disease Service: GI Med/Onc

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: ○ 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

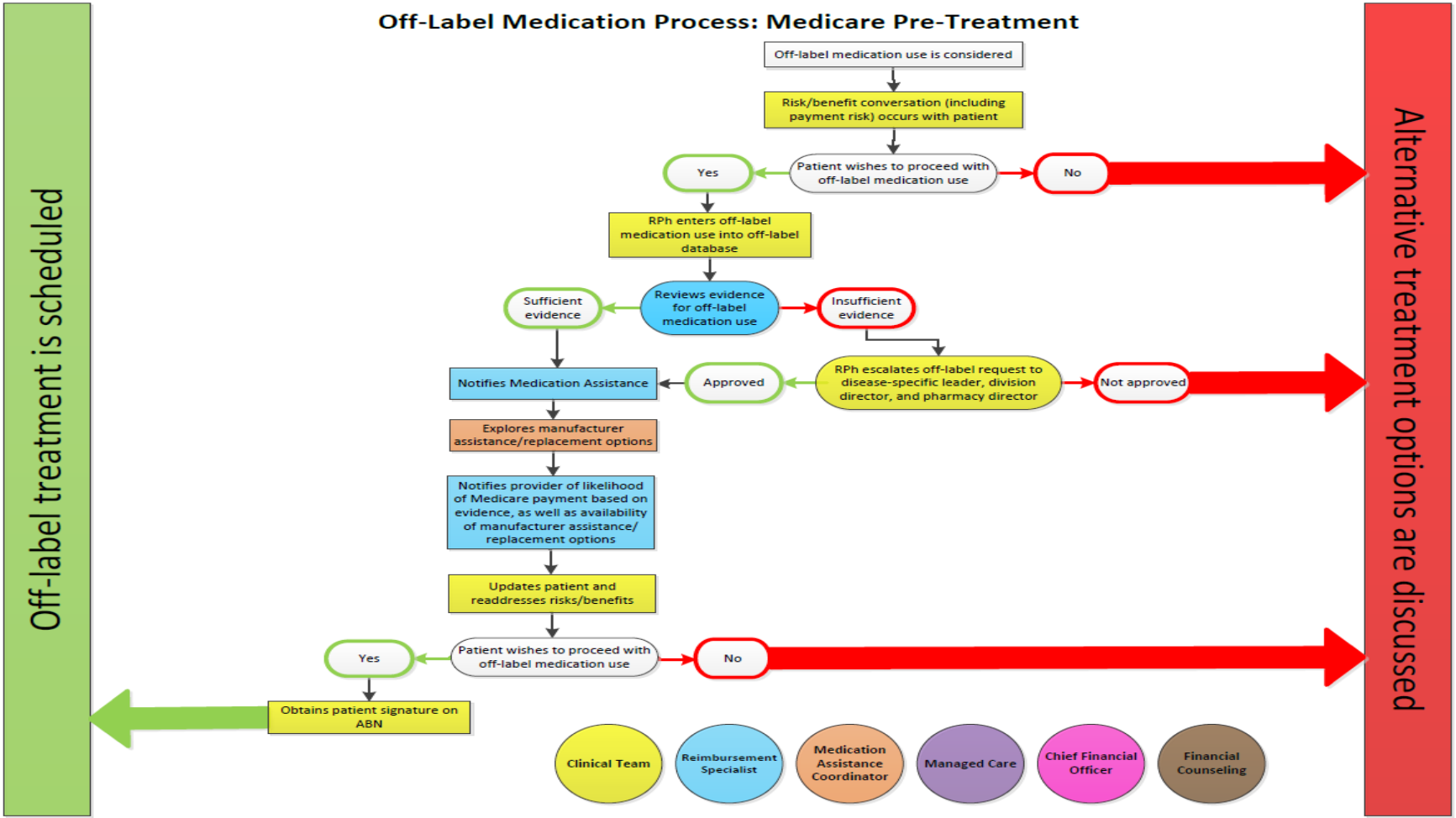
CLAIM DETAILS	
Claim status: ○ Patient receiving medication ◉ Pending payment ○ Denied-pending appeal ○ Appealed ○ Denied-final ○ Completed-paid ○ Not given	
Service Date(s): 07/12/15, 07/19/15	
HAR(s): 07/01/2015, 07/07/2015	
Total Amount Reimbursed: $20,345.00	
Bundled or Inpatient: ○ Yes ◉ No	
Reason 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

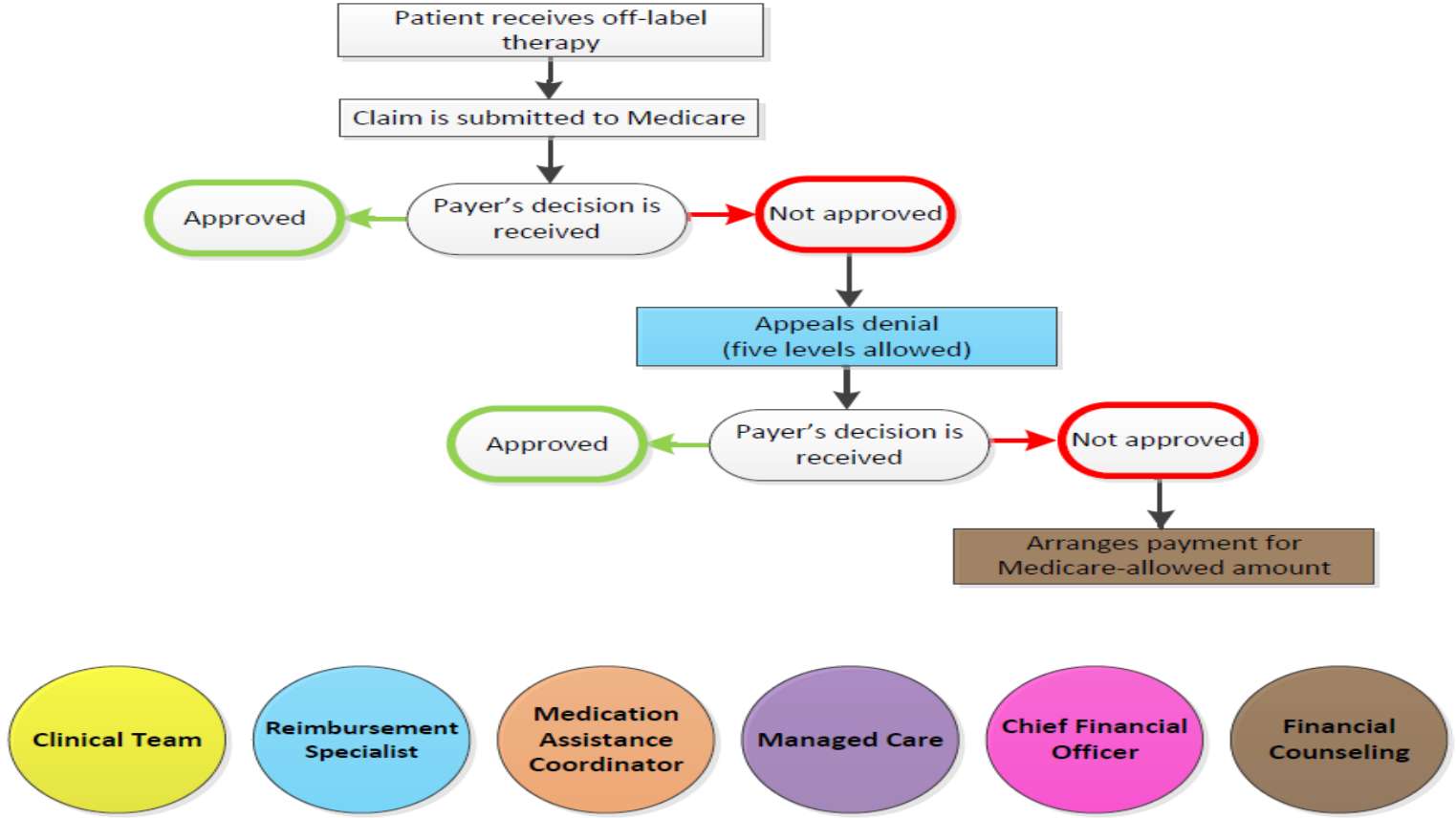
Peer Review Process

- 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

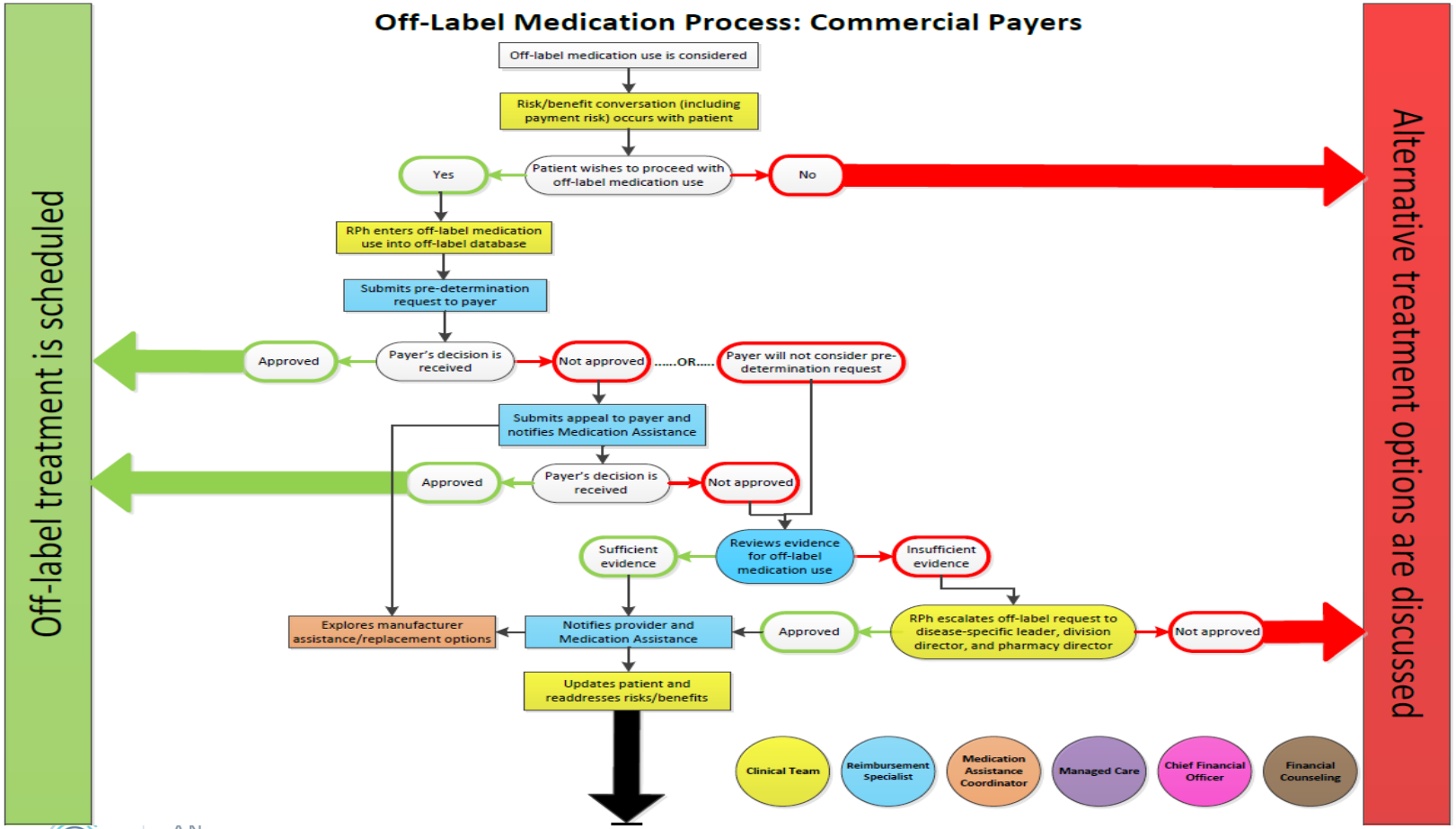
Off-Label Medication Process: Medicare Pre-Treatment



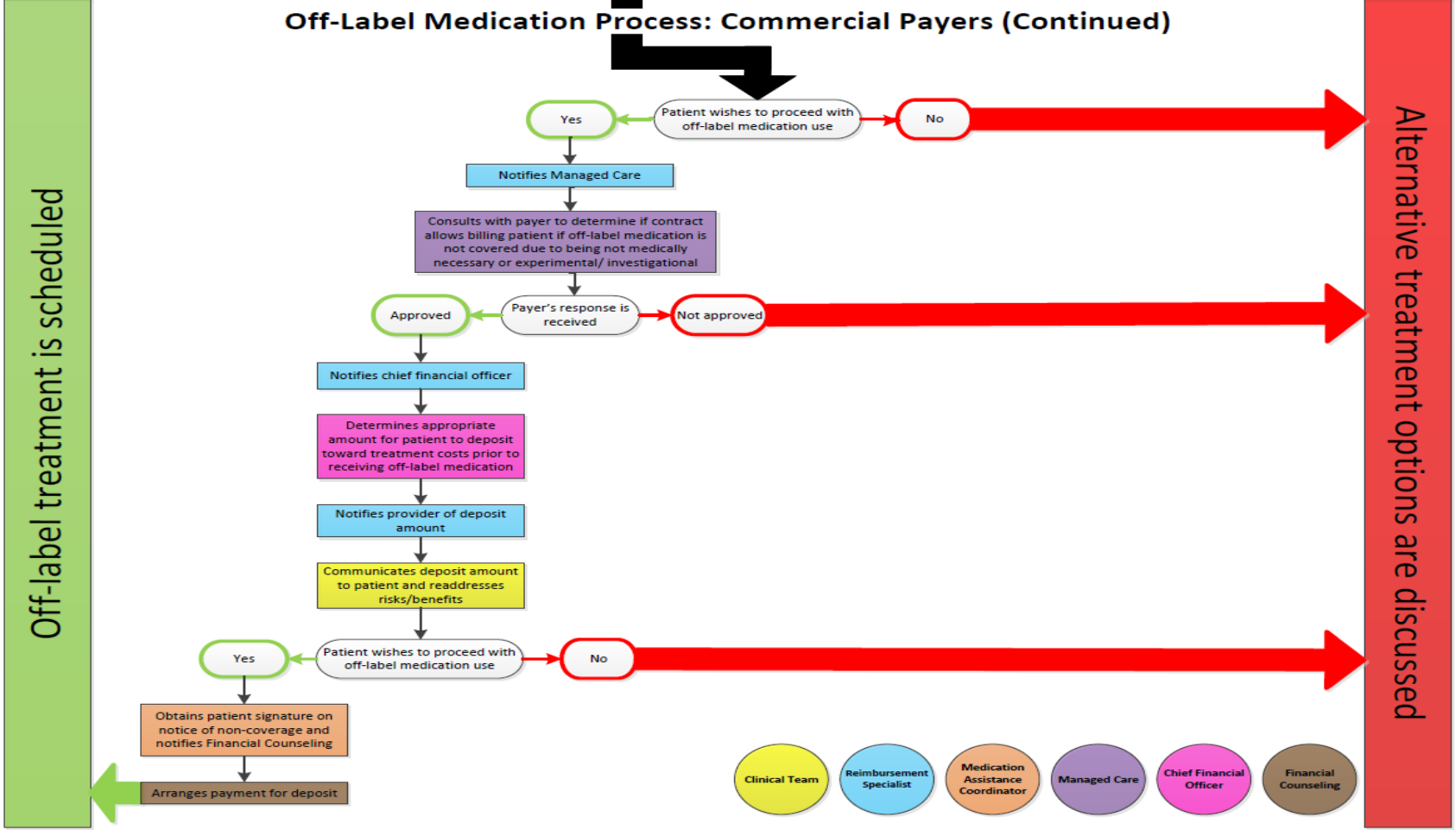
Off-Label Medication Process: Medicare Post-Treatment



Off-Label Medication Process: Commercial Payers



Off-Label Medication Process: Commercial Payers (Continued)



ACCC Resources: Financial Advocacy

The Value of Dedicated Financial Coordinators

http://www.accc-cancer.org/resources/pdf/FAN/FAN-The-Value-of-Dedicated-Financial-Coordinators.pdf

ACCC 2015 Patient Assistance and Reimbursement Guide

http://www.accc-cancer.org/publications/PatientAssistanceGuide.asp

Patient Financial Advocate Position Description

http://www.accc-cancer.org/resources/pdf/FAN/FAN-Patient-Financial-Advocate.pdf

Future Considerations

- Payer ability to keep up with accelerating evidence based new indications (e.g., new lines of therapy, new tumor types)
- Increasing utilization of anti-PD1s in combination with a host of agents (e.g., chemo, targeted, immunotherapeutic)
- Step therapy specifications may be embedded into precert criteria to specify preferred agents as number of marketed anti-PD1s and anti-PDL1s increases
- Potential for coverage policies to be biomarker driven (e.g., PDL1 overexpression)

Panel Discussion

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