

ADVANCES IN
Cancer
IMMUNOTHERAPY™



Effective Practices for Incorporating Immunotherapy into Hospital Operations

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Society for Immunotherapy of Cancer

Disclosures

- No relevant financial relationships to disclose
- I will not be discussing non-FDA approved indications during my presentation.



Overview

- Administrator pearls of wisdom
 - Infrastructure, staffing, responsibilities
 - Role of multidisciplinary team in immunotherapy
- Replicable models
 - Emergency response to triage immunotherapy with immune related adverse events
- Pharmacy effective practices

I-O pipeline and research

- Current products on the market are the “tip of the iceberg” when looking at manufacturers’ Immuno-Oncology (I-O) pipelines
- During the next one to five years, we can expect a new IO product or indication every few months
- Not only new products, but a myriad of new combinations and regimens
- Take advantage of pipeline reports published by various organizations



Strategies for new information

- Immuno-Oncology Champion
 - Identify an “Immuno-Oncology Champion” from among your providers to be the “I-O point person” responsible for all product questions and staff education (can be a physician, advance practice nurse or pharmacist)
- Education group
 - 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
- Staff education
 - Proactively update staff on new information and consider use of manufacturer-provided resources including on-site training/education



Emergency Response

- I-O agents have an adverse event profile that differs from those associated with chemotherapy or commonly used biologic agents
- Staff charged with 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



Emergency Response

- Develop protocols
 - 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
- Patient education
 - Educate all patients on an I-O therapy to clearly identify themselves as such; make sure that these patients can be quickly identified as being on an I-O therapy in their medical record
- Staff education
 - Ensure 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



Manage reimbursement/finances

- New to market I-O agents may not yet have specific J-Code
 - Ensure process is in place for appropriate management/billing until J-Code is assigned or in the case of Hospital Outpatient Prospective Payment Services a C-Code (Temporary = C9399)
- Identify a point person from within your financial or reimbursement staff to focus on I-O agents and understand the nuances of the various patient support programs
 - Manufacturer replacement programs, co-pay support programs, co-pay foundations, and patient assistance programs
- 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.

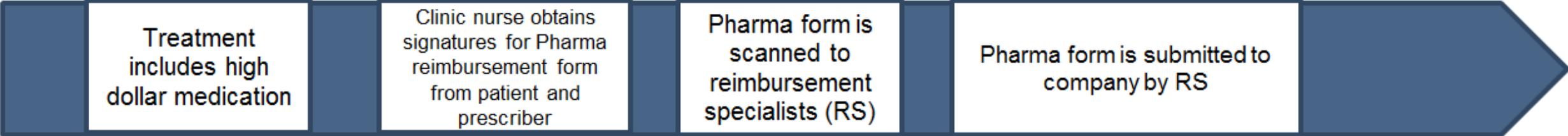


Develop approval process

- High dollar medication approval process
 - Full benefits investigation, utilize pharma services if offered and allowed per hospital/institution policy
 - Prioritize staff resources to enroll every viable patient into a support program, regardless of on or off-label
- Robust off-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
 - Peer review process for appeal if needed



High Dollar Process



On Label Request

Off Label Request

Full benefits investigation performed by Pharma services and referral to copay and PMAP resources provided if necessary

Patient coverage verified by RS

Refer to Off label policy and procedure

Request submitted to payer for approval

Denied

Approved

RS communicates with pharmacist and team once authorization is approved

Patient scheduled for therapy

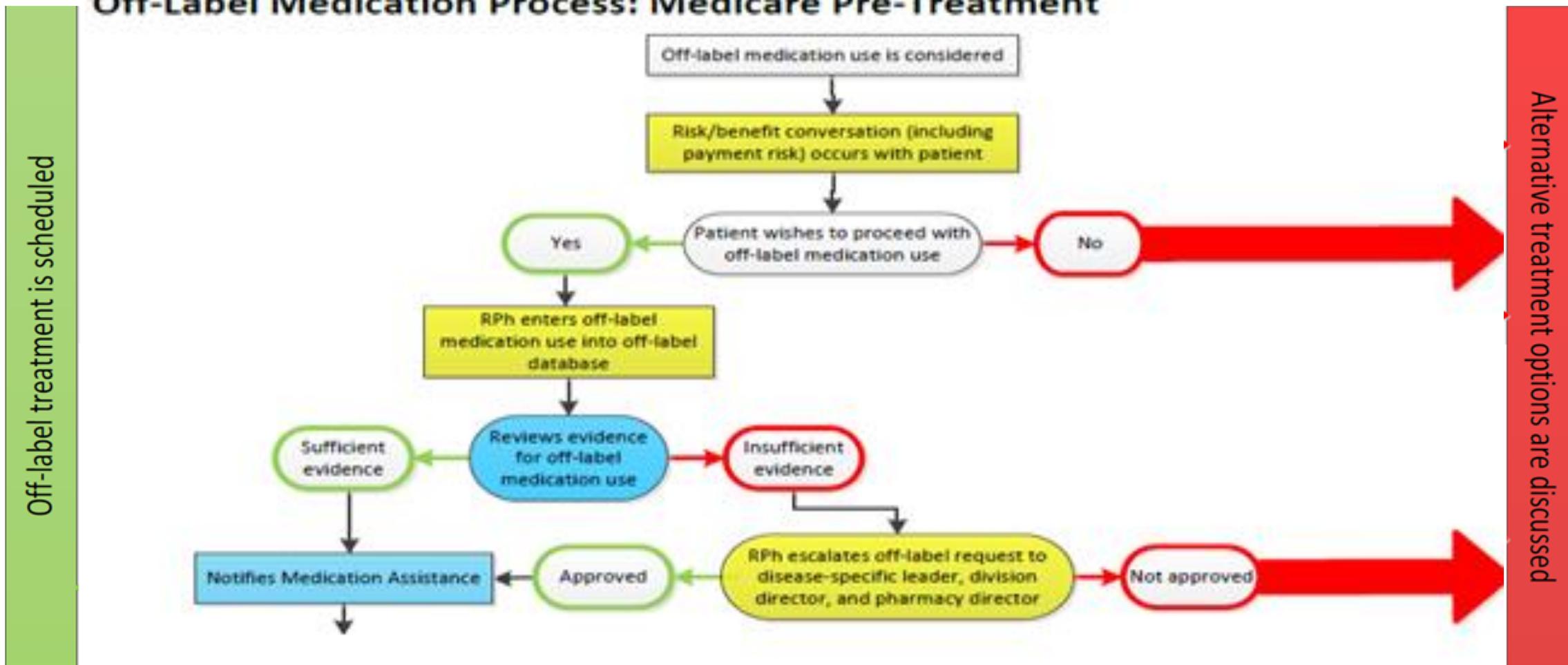
Follow account to ensure payment and application of copay assistance

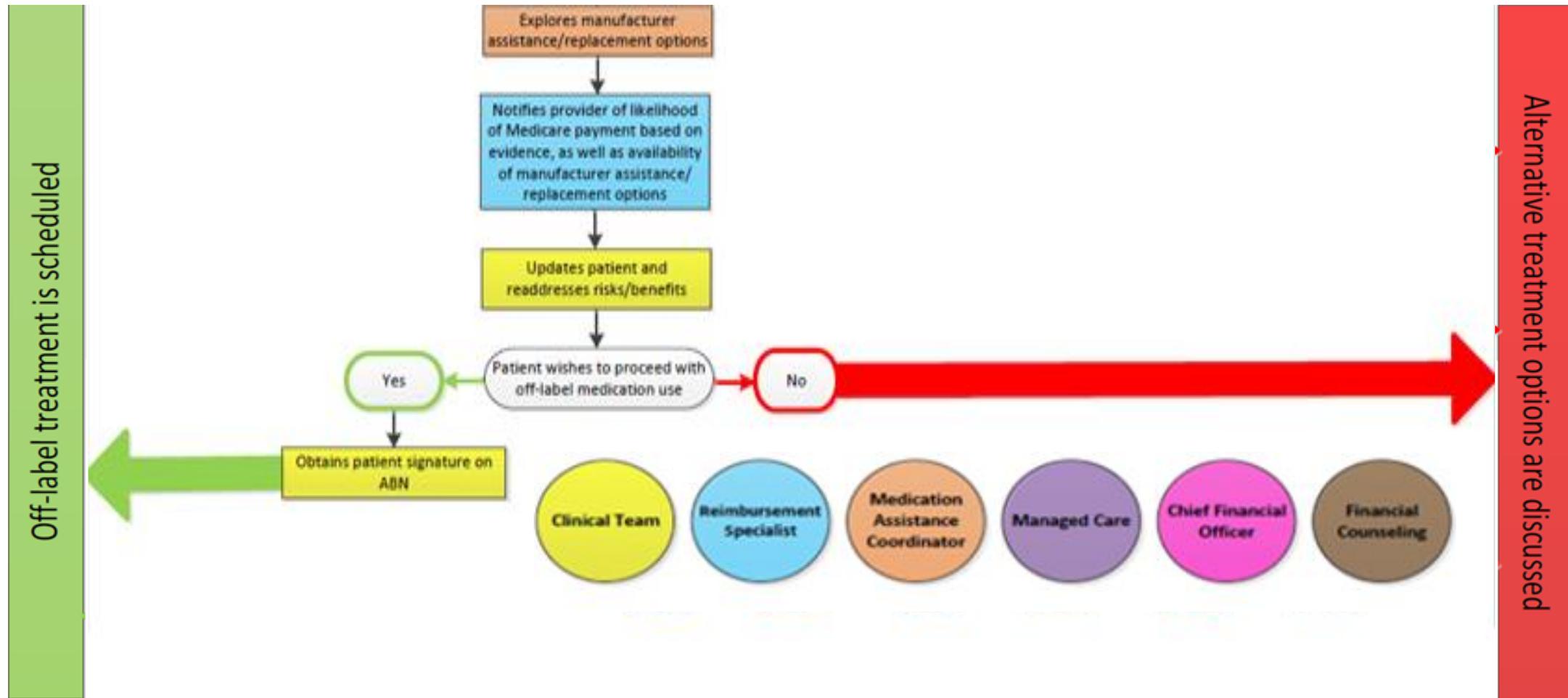
Medication Assistance Program Coordinator (MAPC) speaks with patient about benefits and need for copay or PMAP assistance

MAPC assists with copay or PMAP assistance

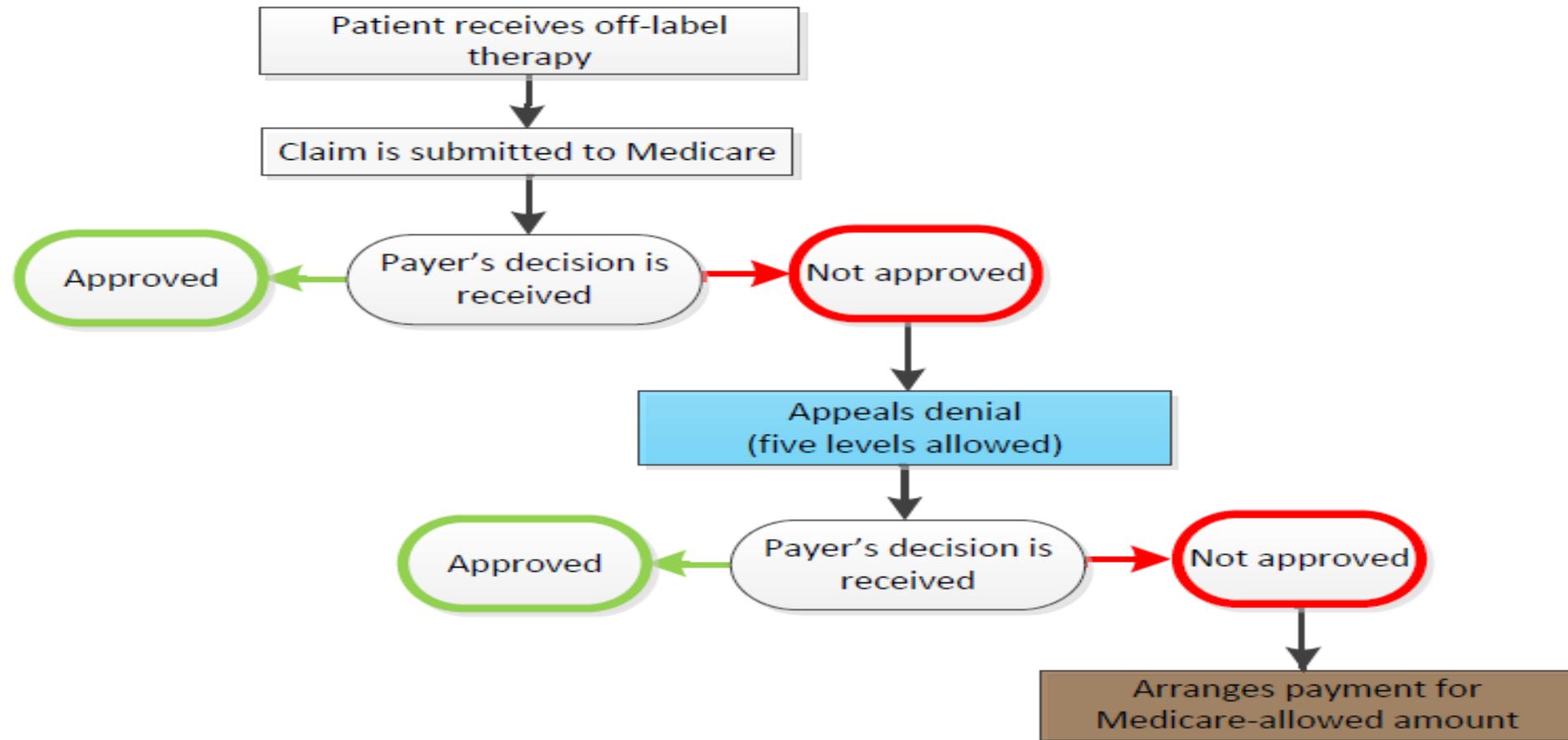
Coordinate with business office to submit copay grants

Off-Label Medication Process: Medicare Pre-Treatment





Off-Label Medication Process: Medicare Post-Treatment



Clinical Team

Reimbursement Specialist

Medication Assistance Coordinator

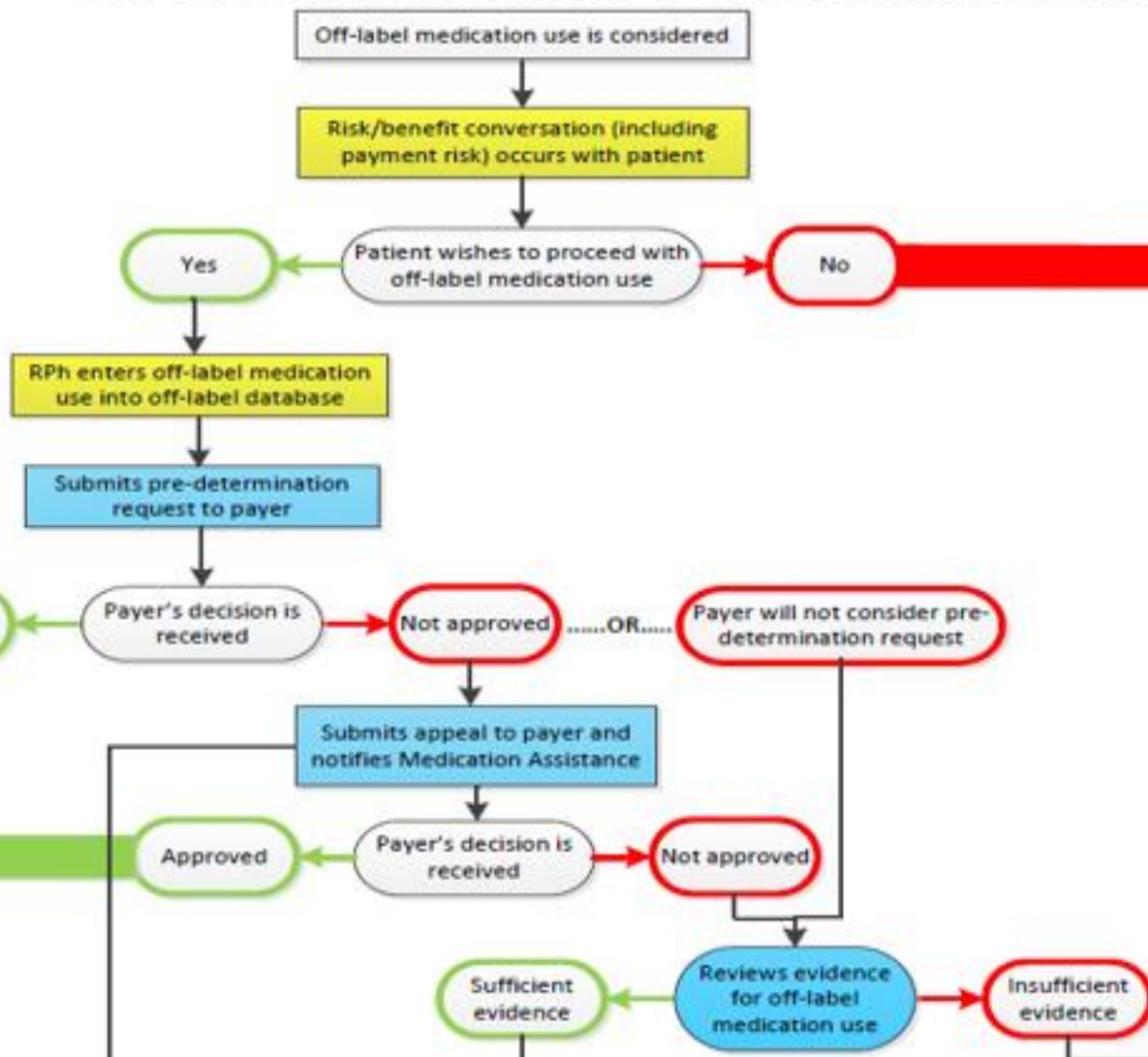
Managed Care

Chief Financial Officer

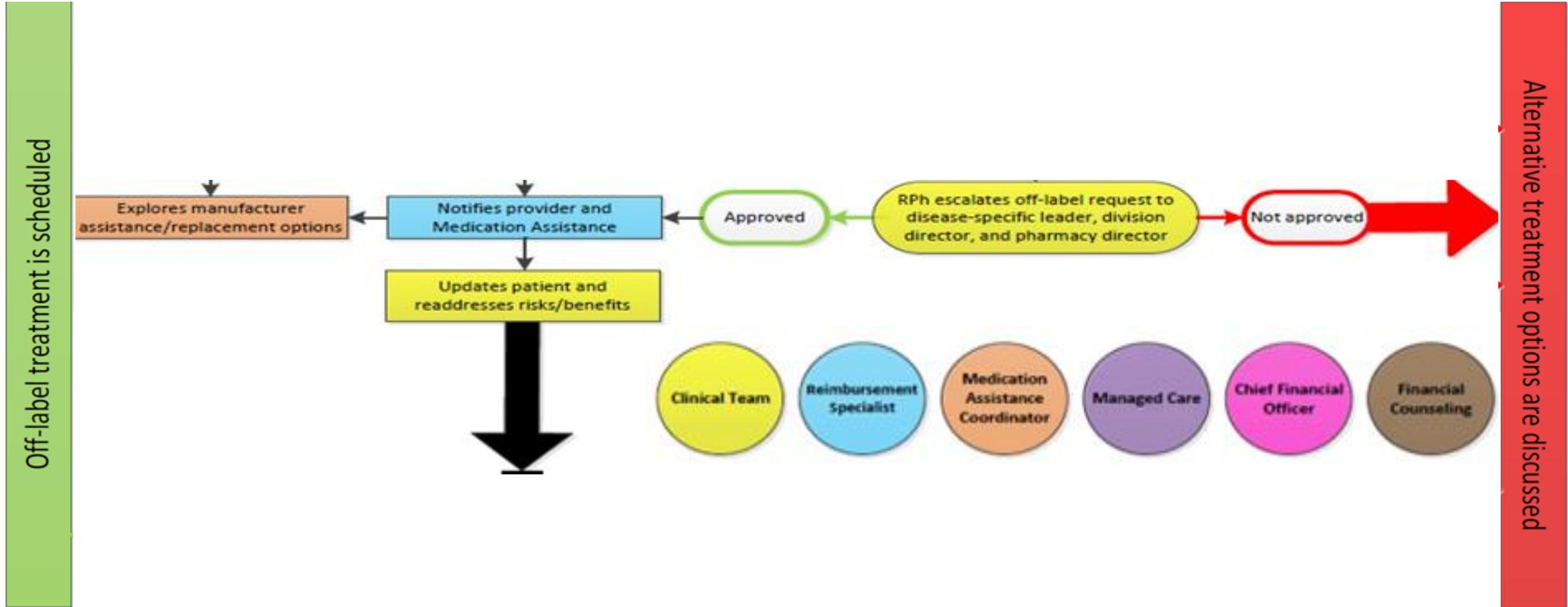
Financial Counseling

Off-Label Medication Process: Commercial Payers

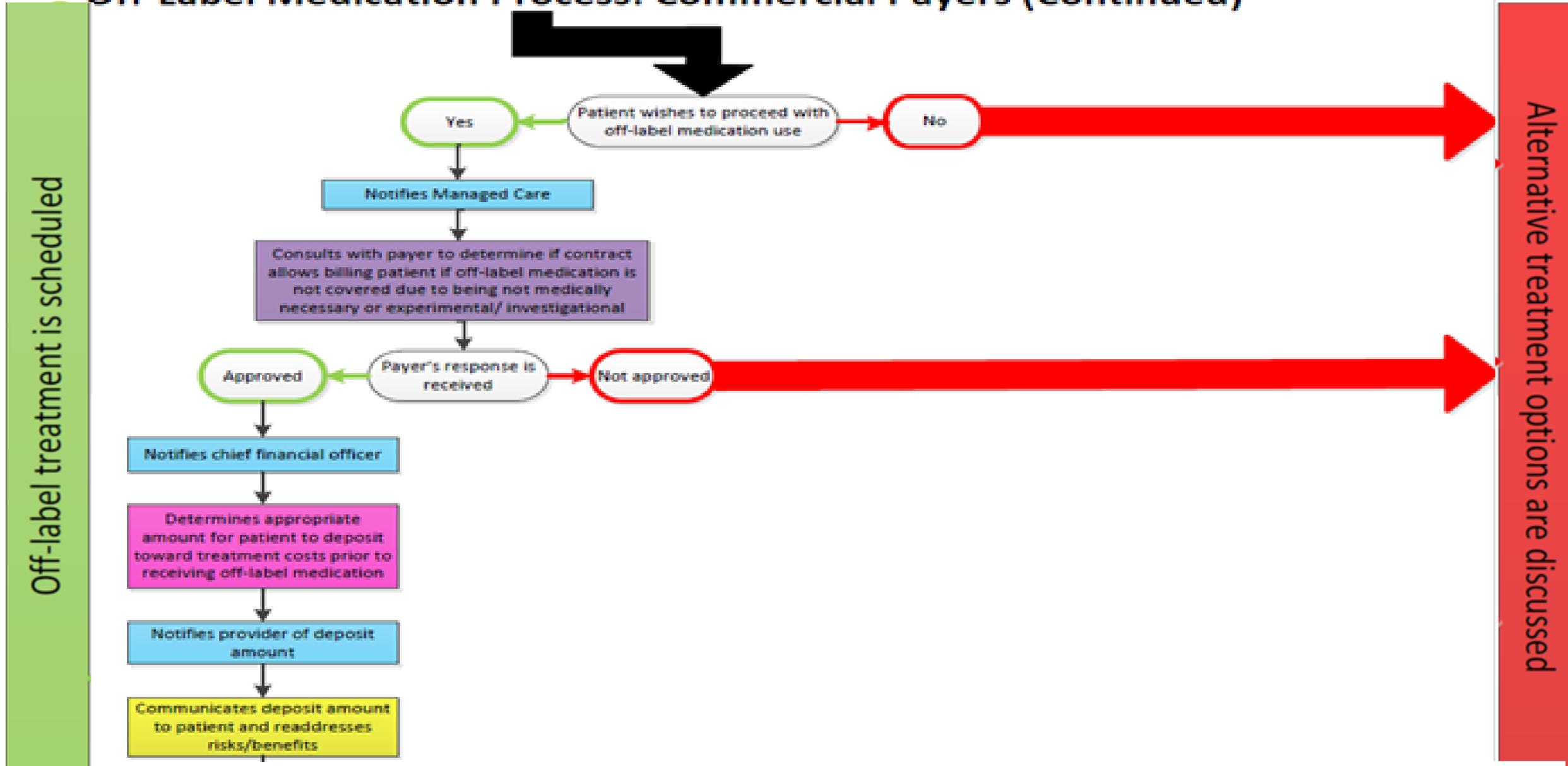
Off-label treatment is scheduled



Alternative treatment options are discussed

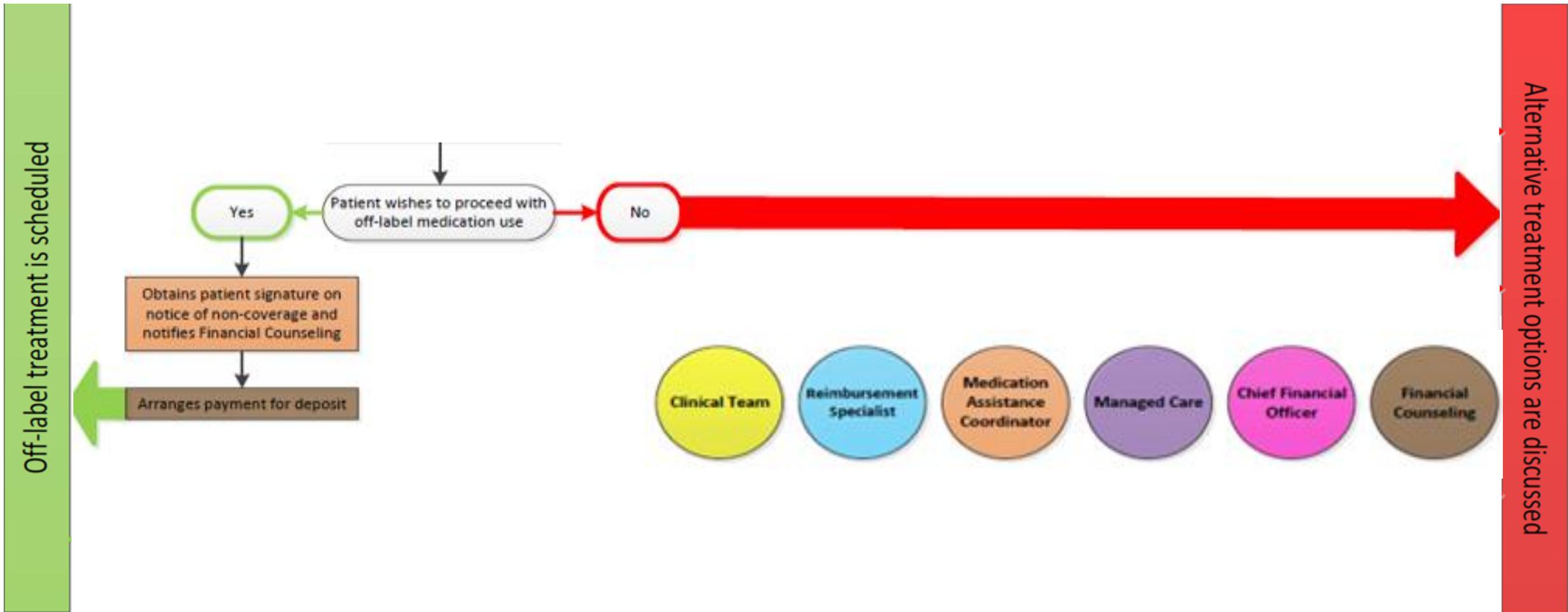


Off-Label Medication Process: Commercial Payers (Continued)



Off-label treatment is scheduled

Alternative treatment options are discussed



Dedicate resources payer approval process

- Taking a team approach to immunotherapy payer approval process is key
- Key players:
 - Physician/Advanced Practice Provider (CNP or PA)
 - Pharmacist
 - Reimbursement Specialist
- Effective and traceable form of communication is essential

Payer approval process

- Physician/Advanced Practice Provider (CNP or PA)
 - Identify patient who may benefit from I-O therapy
 - Discuss rationale for off-label use if applicable
 - Provide additional primary literature support if necessary
 - Participate in peer to peer conversations if needed

Payer approval process

- Pharmacist role
 - Retrieve supporting literature
 - Review CMS approved compendia and NCD/LCD
 - Enter request into off-label use database or spreadsheet so all off label use can be tracked and followed
 - Entry should trigger alerts to pharmacy director, P&T committee chair and reimbursement specialist team

Payer approval 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

Payer approval process

- Reimbursement Specialist role
 - Draft letter of medical necessity (*prescriber to sign*)
 - 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

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
- Resource intense
 - Clinical team (physicians, pharmacists, APPs)
 - Reimbursement staff



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

SUMMARY

- It appears that the IO pipeline is very robust with new agents and a myriad indications nearly overwhelming the system in the coming years
- Remembering that these new IO agents are very expensive, its is even more important that all therapy is authorized and patient support is mobilized
- Develop a method to track any off-label requests and their reimbursement or provision for free