

ADVANCES IN
Cancer
IMMUNOTHERAPY™



Effective Practices for Incorporating Immunotherapy into Hospital Operations

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Society for Immunotherapy of Cancer

Disclosures

- Merck & Co., Inc., Eisai, Inc., Fees for Non-CME/CE Services Received Directly from a Commercial Interest *or their Agents*
- 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

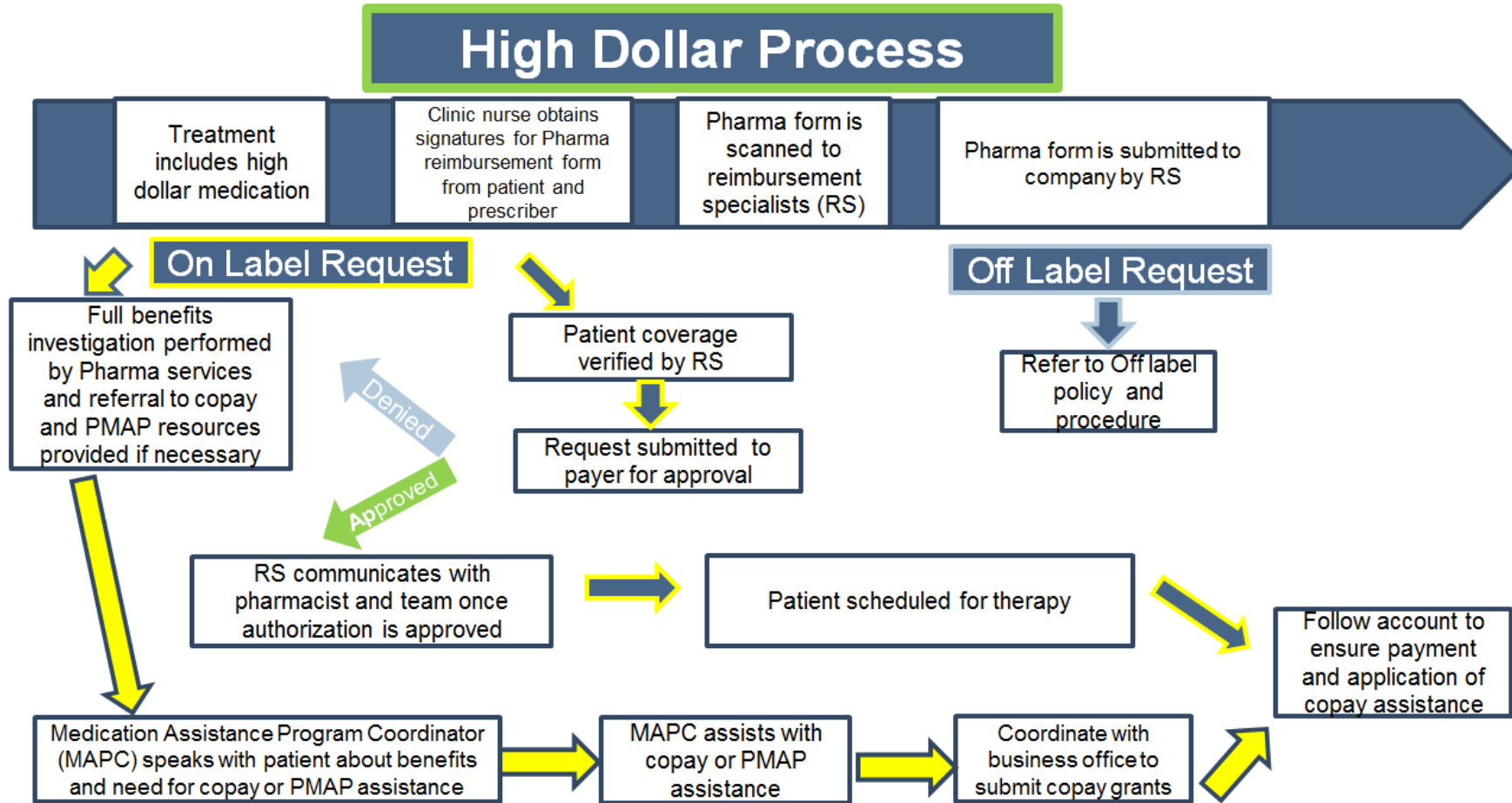
- New to market I-O agents may not yet have specific J-Code
 - Ensure process is in place for appropriate management/billing until J-Code is assigned or in the case of Hospital Outpatient Prospective Payment Services a C-Code (Temporary = C9399)
- Identify a point person from within your financial or 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.

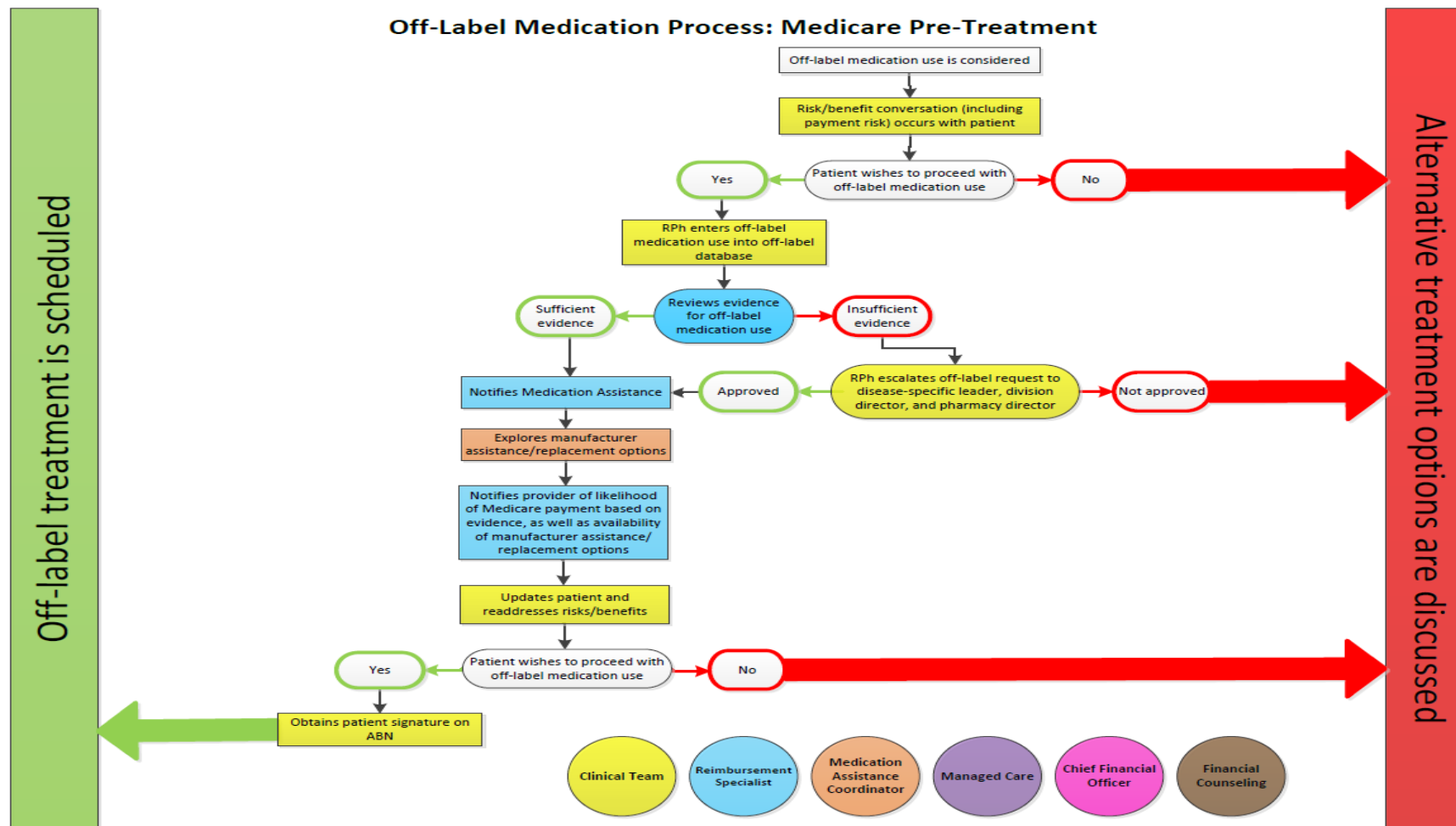


Develop approval process

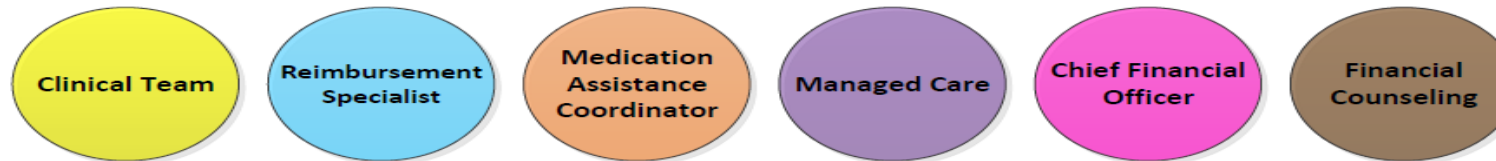
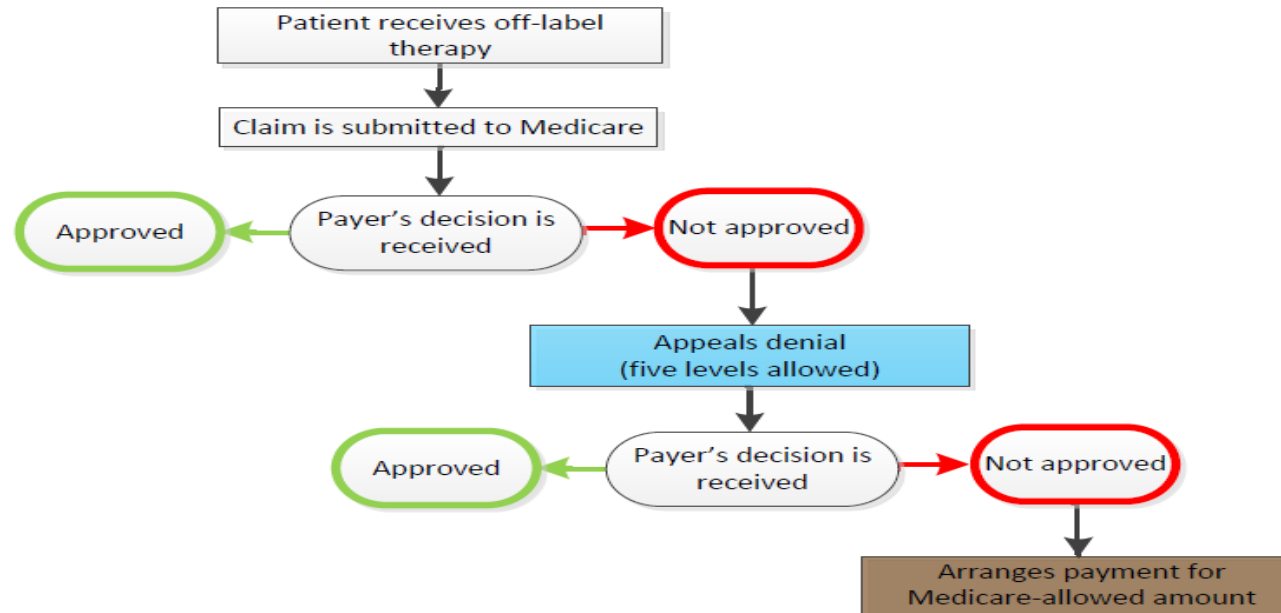
- High dollar medication approval process
 - Full benefits investigation, utilize pharma services if offered and allowed per hospital/institution policy
 - Prioritize staff resources to enroll every viable patient into a support program, regardless of on or off-label
- Robust off-label policy and procedure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

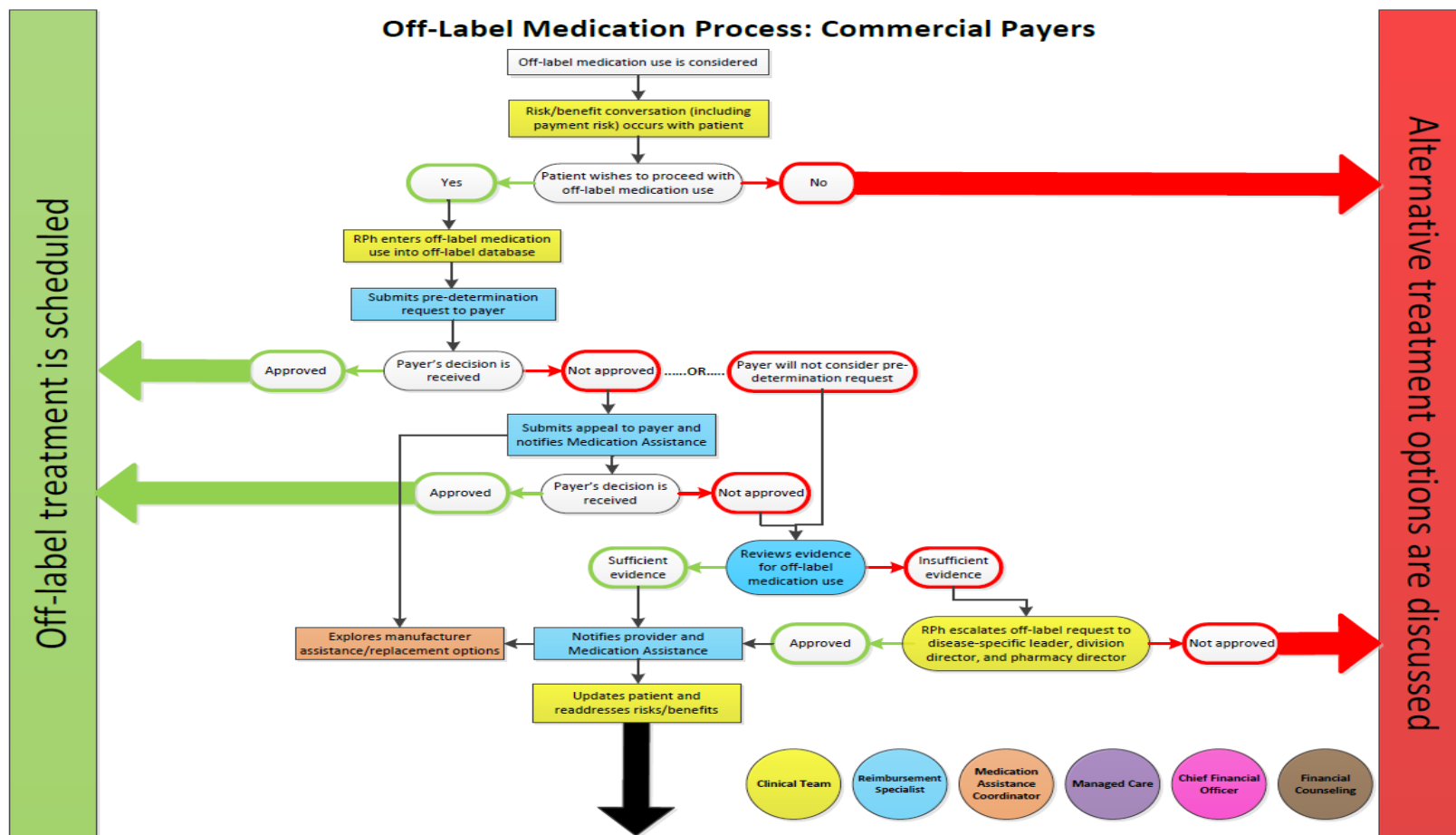


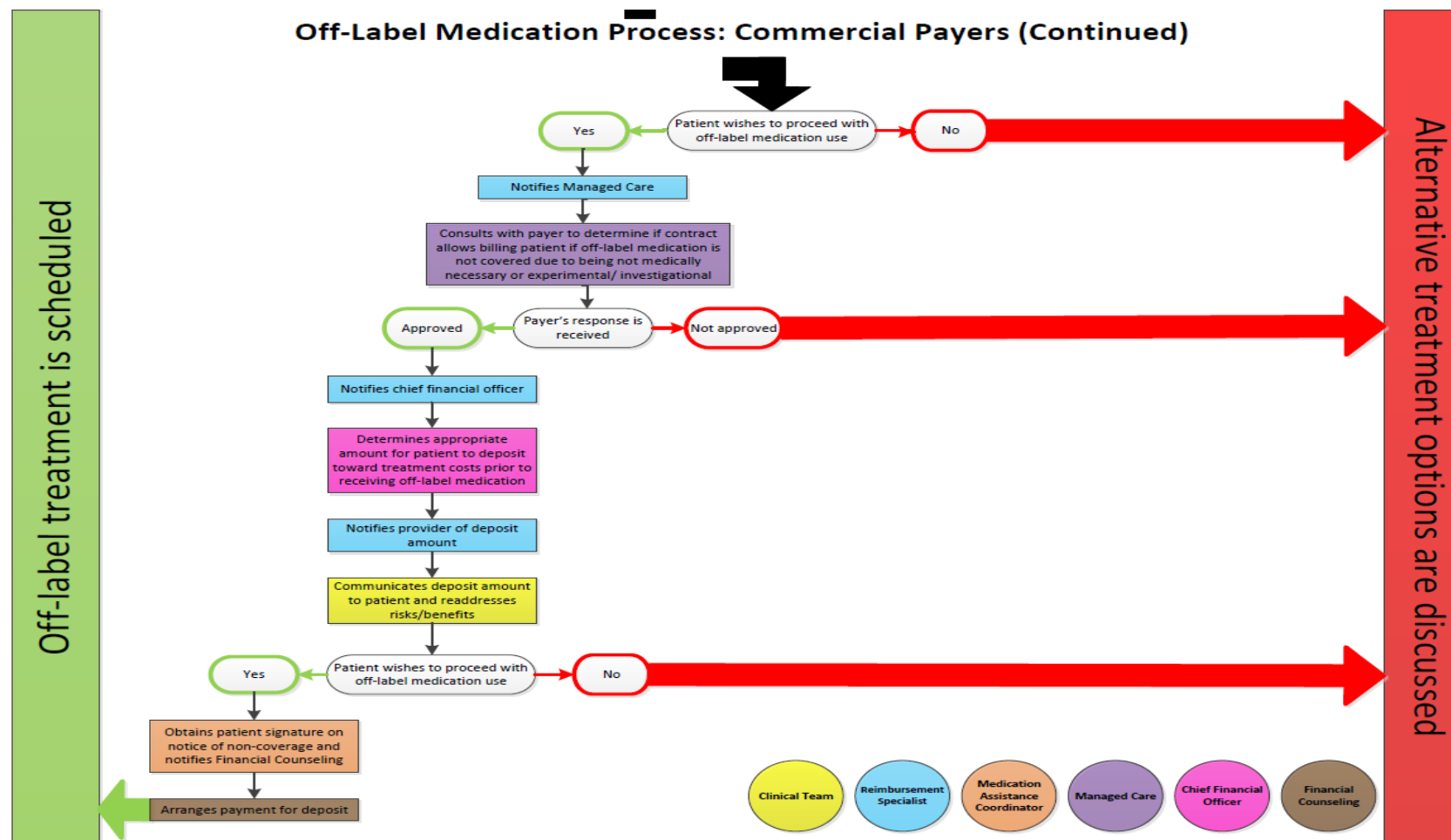




Off-Label Medication Process: Medicare Post-Treatment







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, it 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