ADVANCES IN Cancer IMMUNOTHERAPY™

Effective Practices for Incorporating Immunotherapy into Hospital Operations

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Association of Community Cancer Centers

Society for Immunotherapy of Cancer

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- I *will not* be discussing non-FDA approved indications during my presentation.

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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

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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

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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

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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

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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

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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.

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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

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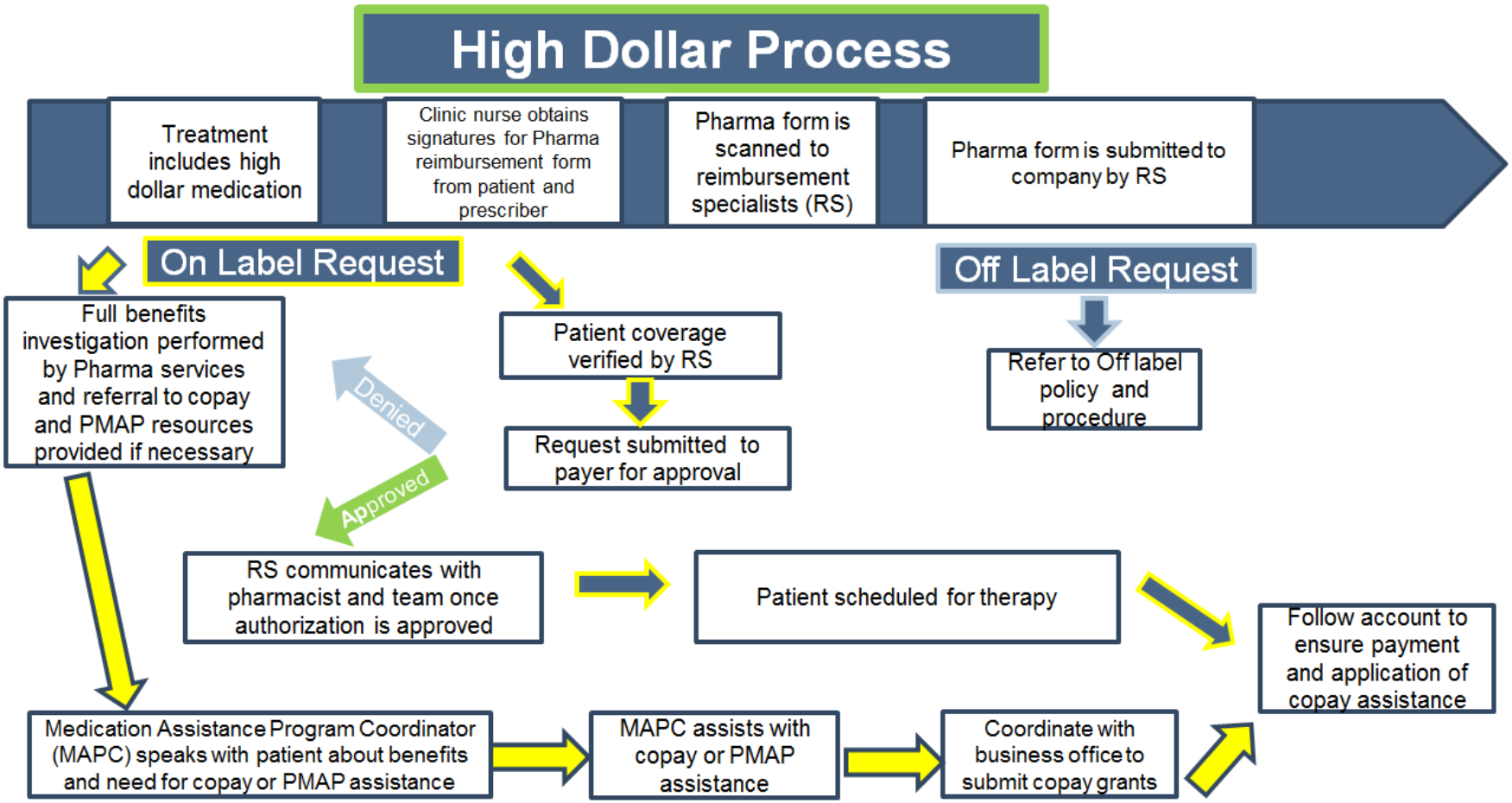
High Dollar Process



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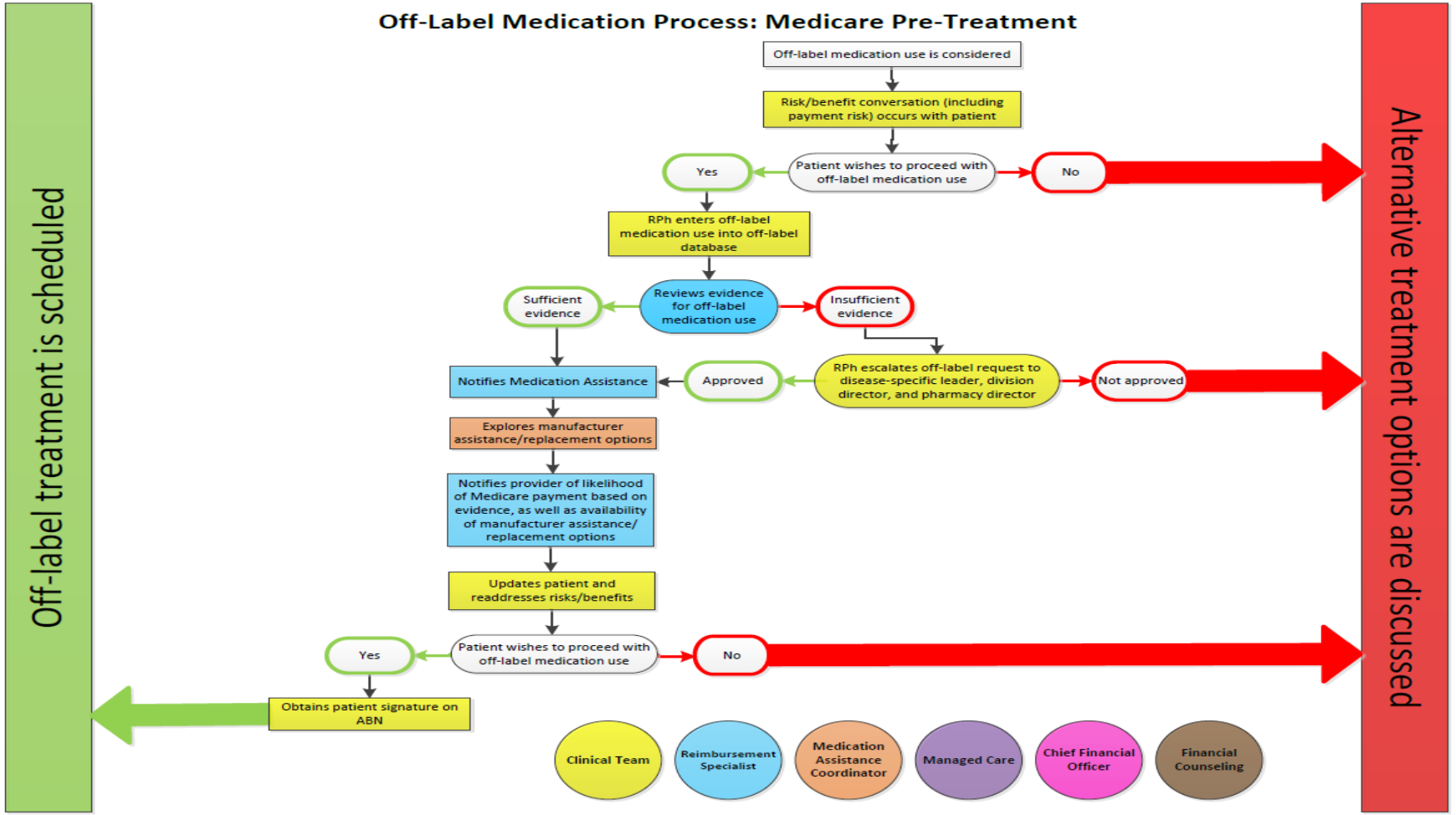

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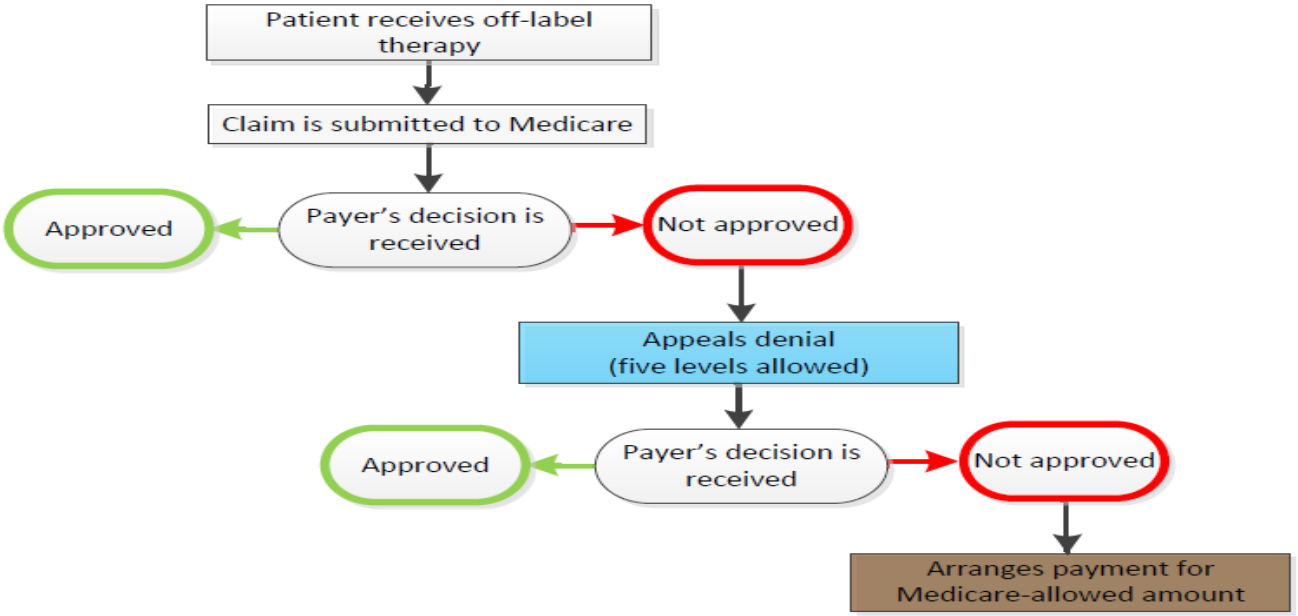
Off-Label Medication Process: Medicare Post-Treatment



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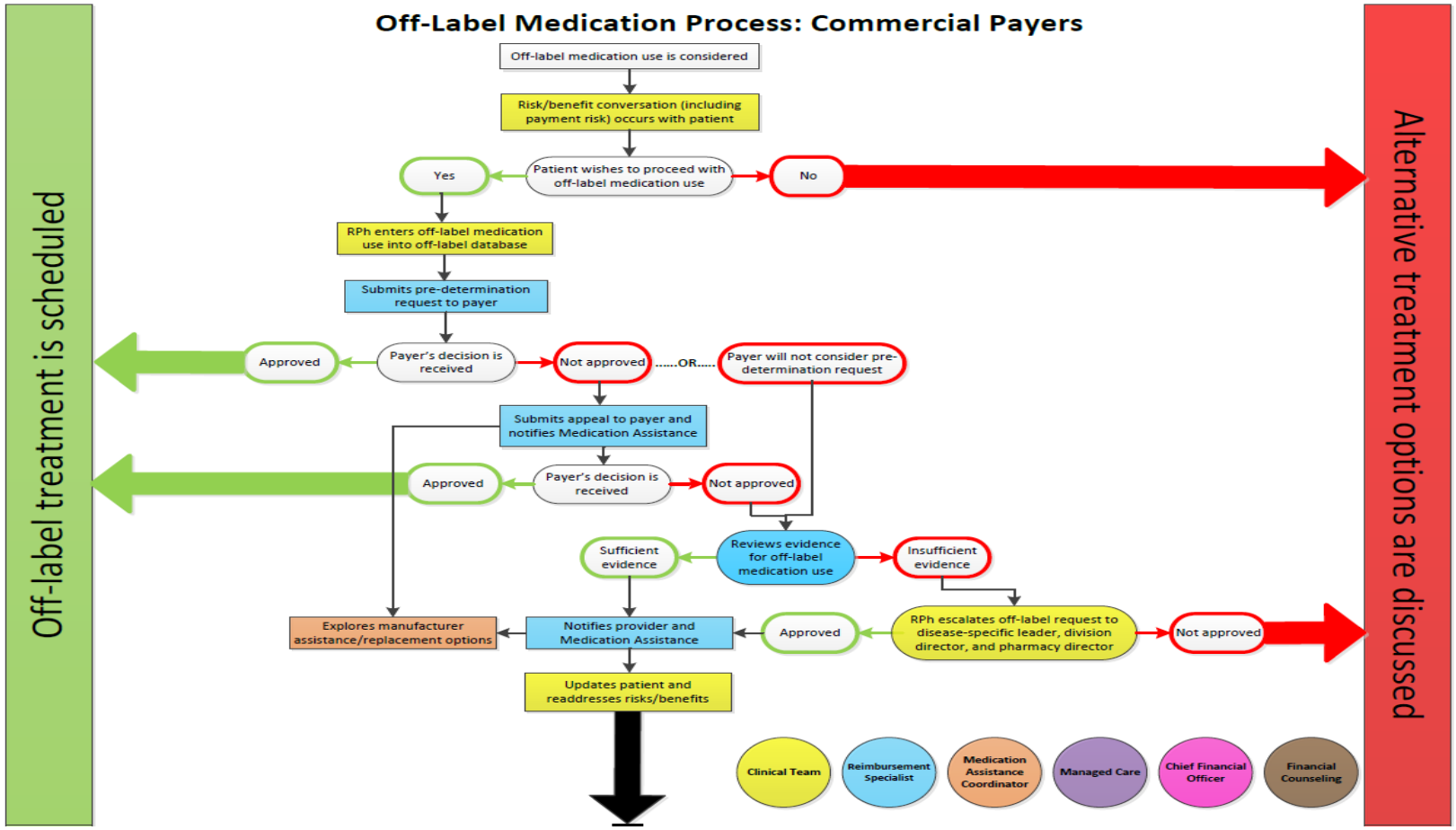

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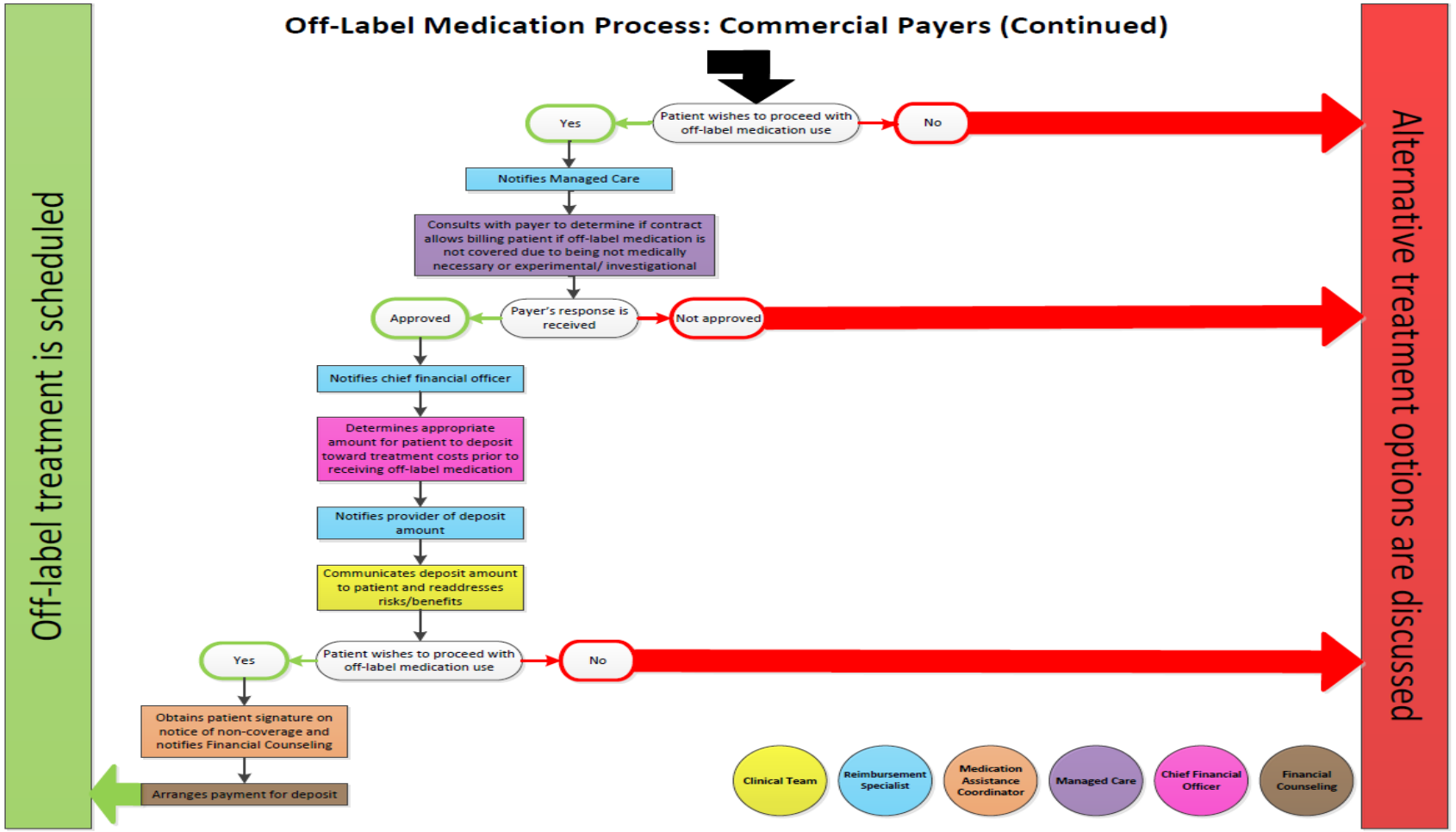

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Dedicate resources payer approval process

- 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

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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

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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

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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

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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

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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

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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

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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