ADVANCES IN Cancer IMMUNOTHERAPY™

Effective Practices for Incorporating Immunotherapy into Hospital Operations

Sigrun Hallmeyer, MD

Director, ALGH Cancer Service Line

Director, ALGH Cancer Survivorship Center

Advocate Lutheran General Hospital Park Ridge, IL

American Academy of Emergency Medicine

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Disclosures

- Speaker (BMS; Pfizer [non-promotional])
- Advisor (BMS, Merck, Novartis, Cardinal Health)
- 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
  - Contracting, purchasing, inventory control, and patient review take on a much more important role

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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 be 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 benefits verification programs, replacement programs, co-pay support programs, co-pay foundations, and patient assistance programs
- Ensure your practice has sufficient Patient Advocacy
  - 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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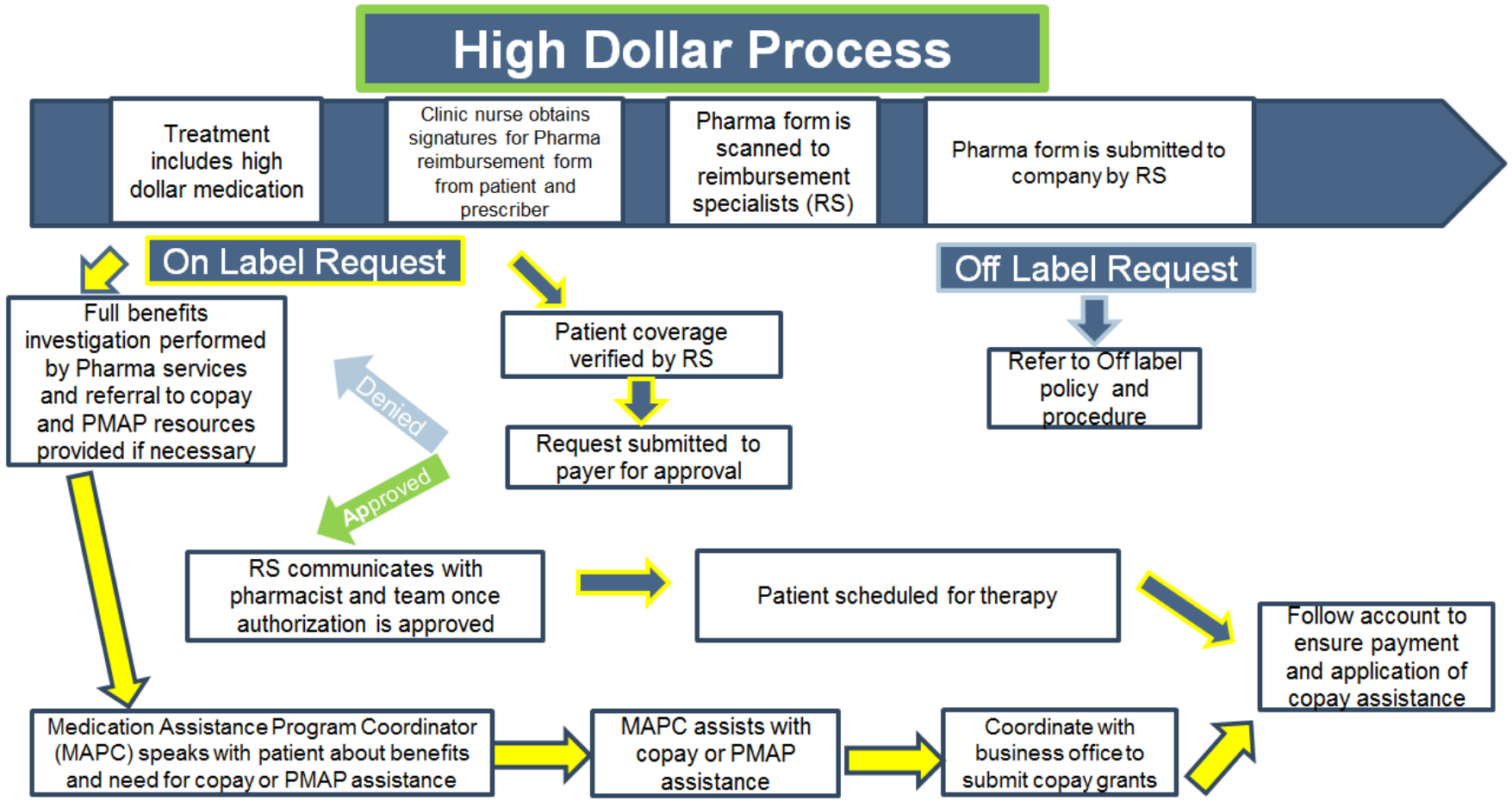
High Dollar Process



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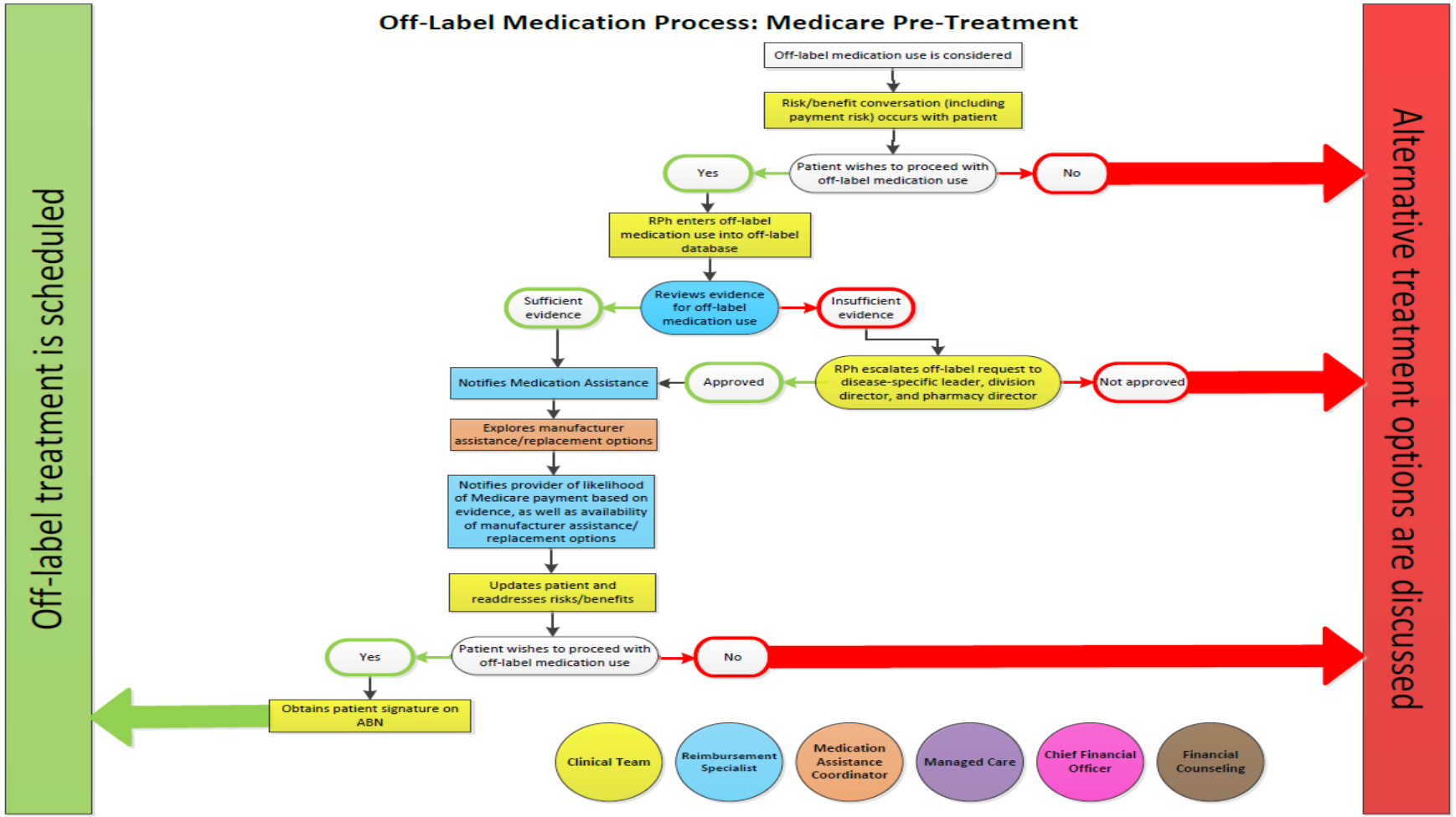

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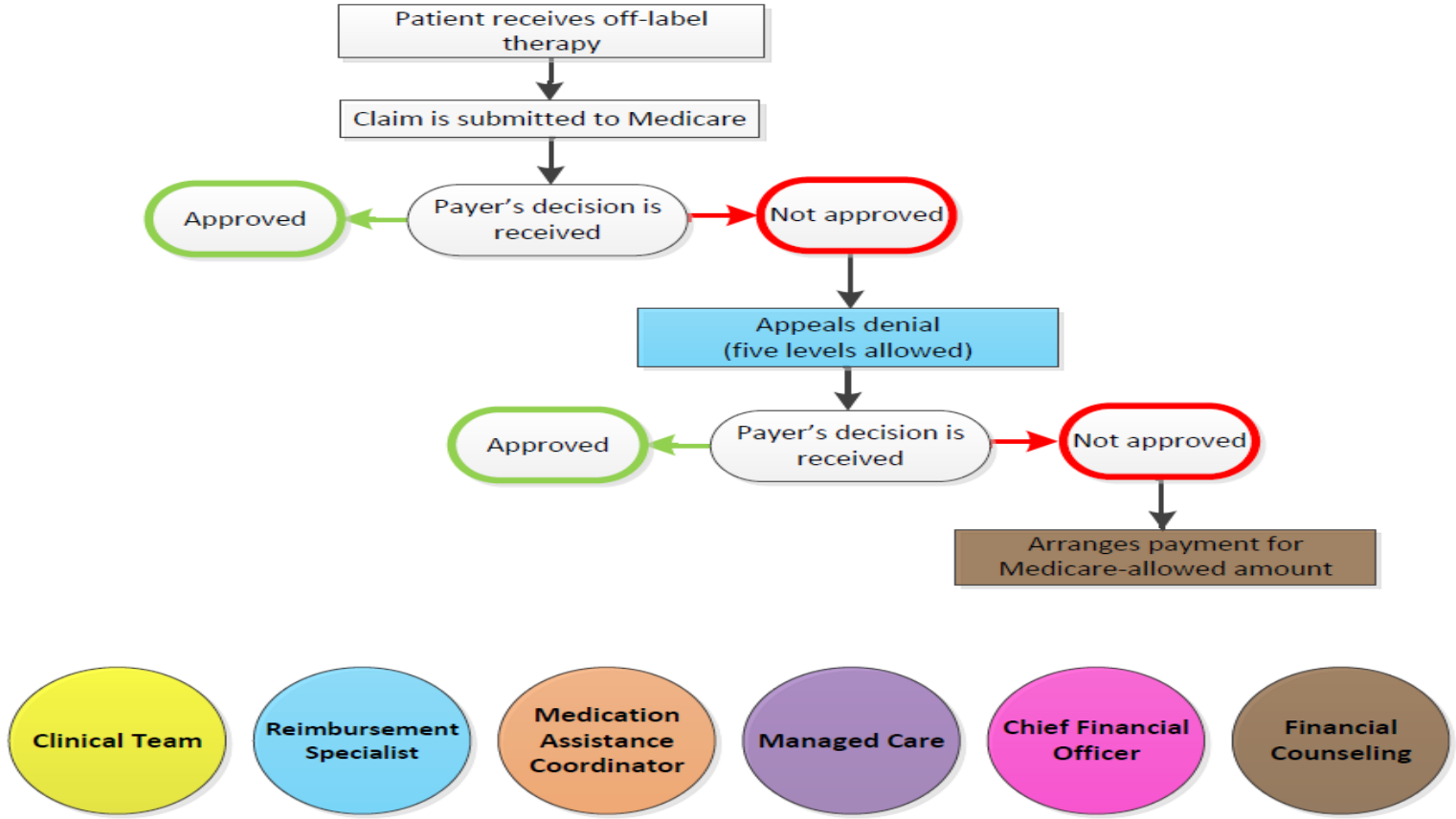
Off-Label Medication Process: Medicare Post-Treatment



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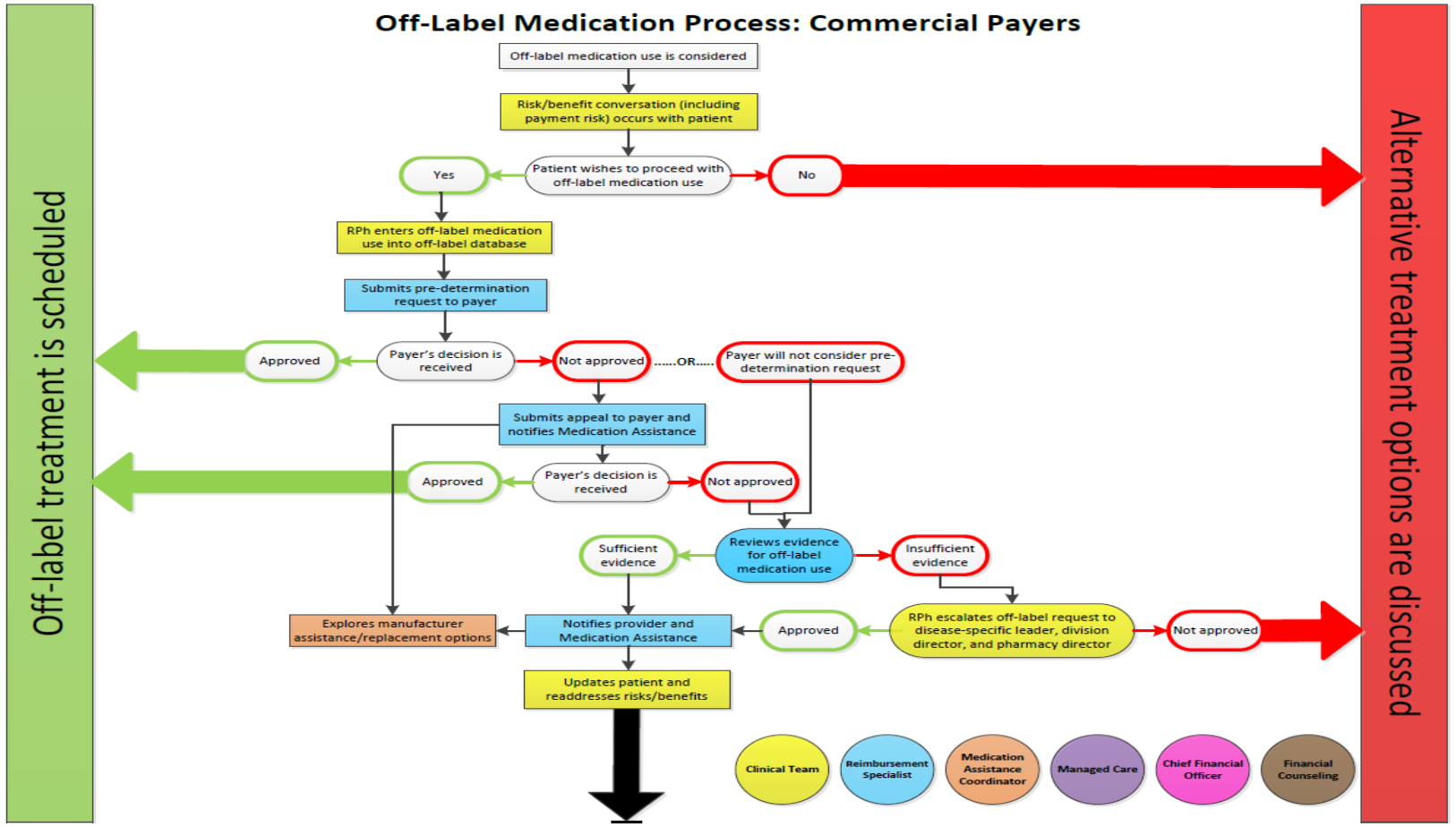

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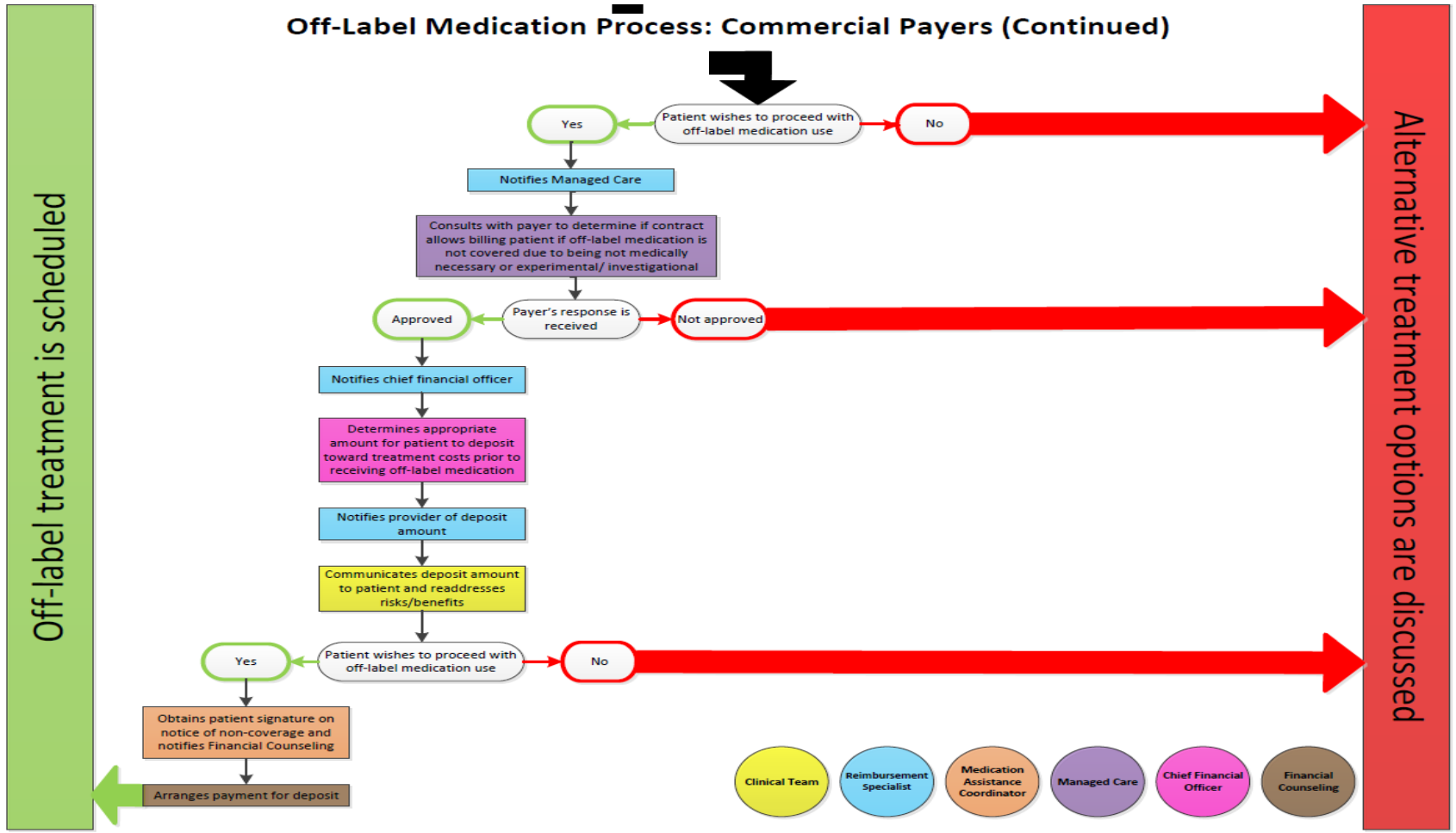

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Dedicate resources to the payer approval process

- 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
- EMR systems not set up for this type of process
- 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