sitc Society for Immunotherapy of Cancer

ADVANCES IN Cancer IMMUNOTHERAPY™

Practical Barriers in Cancer Immunotherapy Treatment

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AAEM AMERICAN ACADEMY OF EMERGENCY MEDICINE CHAMPION OF THE EMERGENCY PHYSICIAN

ACCC Association of Community Cancer Centers

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Disclosures

- I have served on advisory boards for Merck and BMS
- I will not be discussing non-FDA approved indications during my presentation.

IO 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 physician, advance practice nurse of pharmacists)
- 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 recourses including on-site training/education

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

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.

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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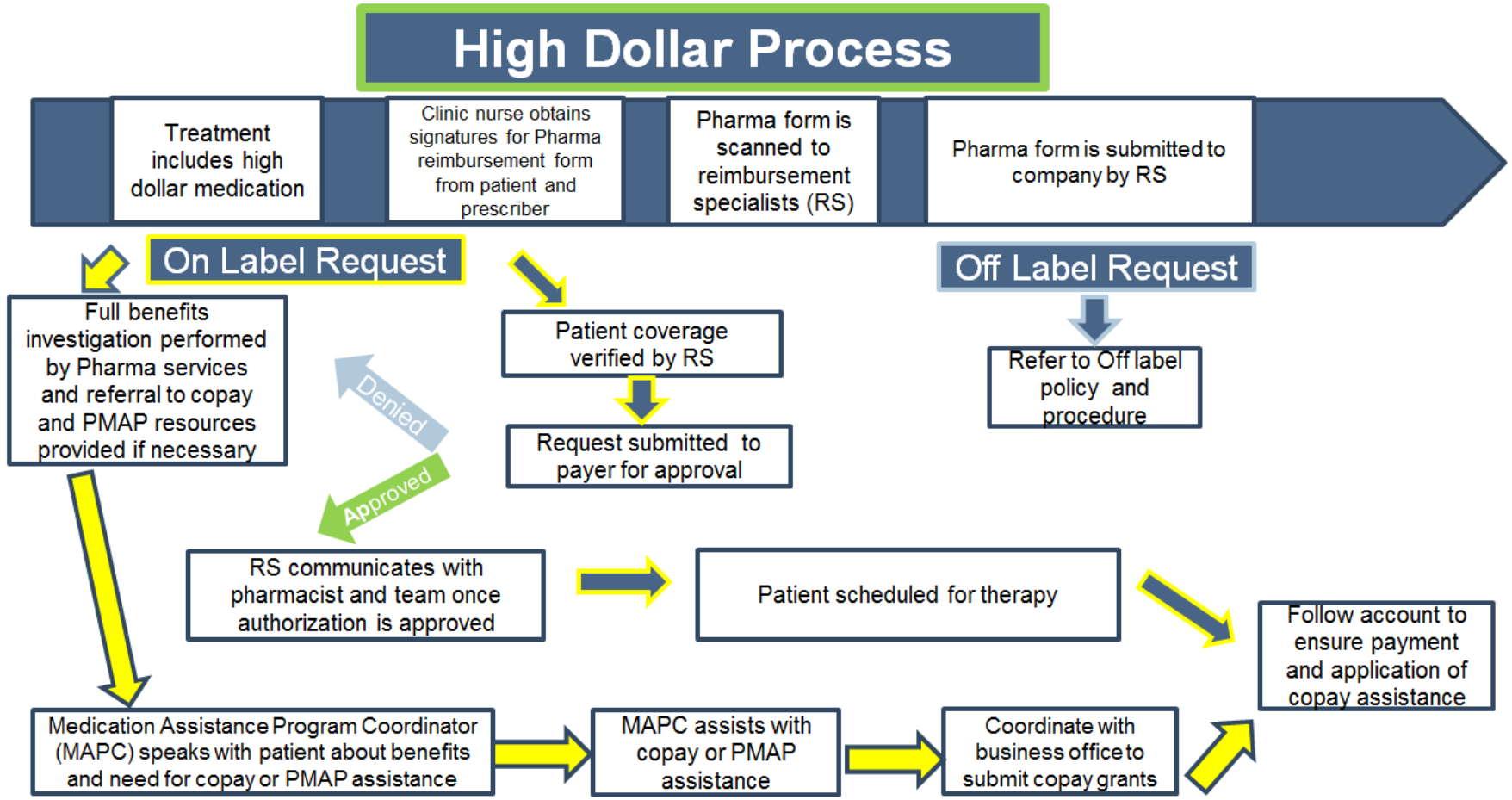
US Based Payer Considerations

High Dollar Process



Medicare

- Most Medicare Administrative Contractors (MAC) have at least one I-O agent Local Coverage Determination (LCD)
- Some MAC have separate LCD for all agents
  - CGS published atezolizumab LCD within the first six weeks of release of the agent
- No successful reimbursement outside the FDA label indications
- No National Coverage Determinations (NCD) to date

Off-Label Medication Process:

Medicare Pre-Treatment

Off-Label Treatment is scheduled

Off-label medication use is considered

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Risk/benefit conversation (including payment risk) occurs with patient

↓

Patient wishes to proceed with off-label medication use

→ **No** → **Alternate treatment options are considered**

↓

Yes

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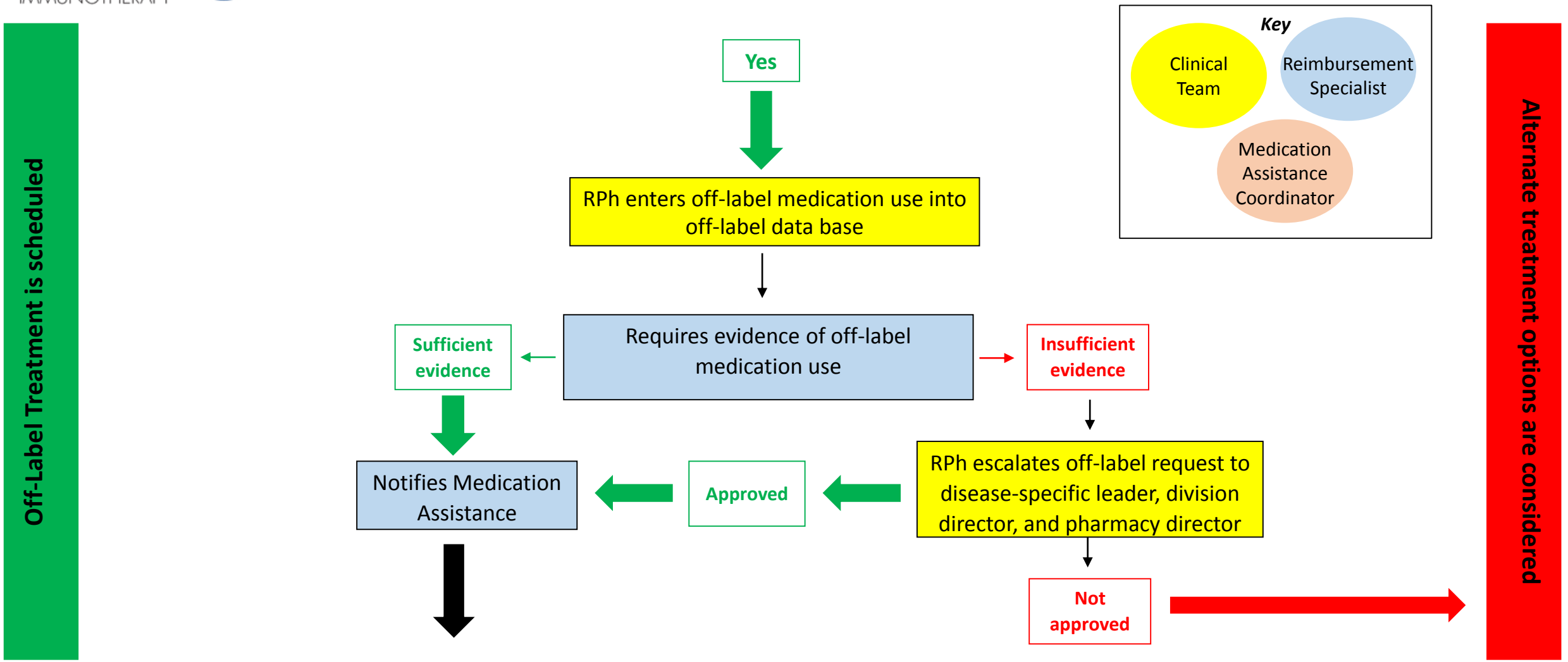
Key

- Clinical Team
- Reimbursement Specialist
- Medication Assistance Coordinator

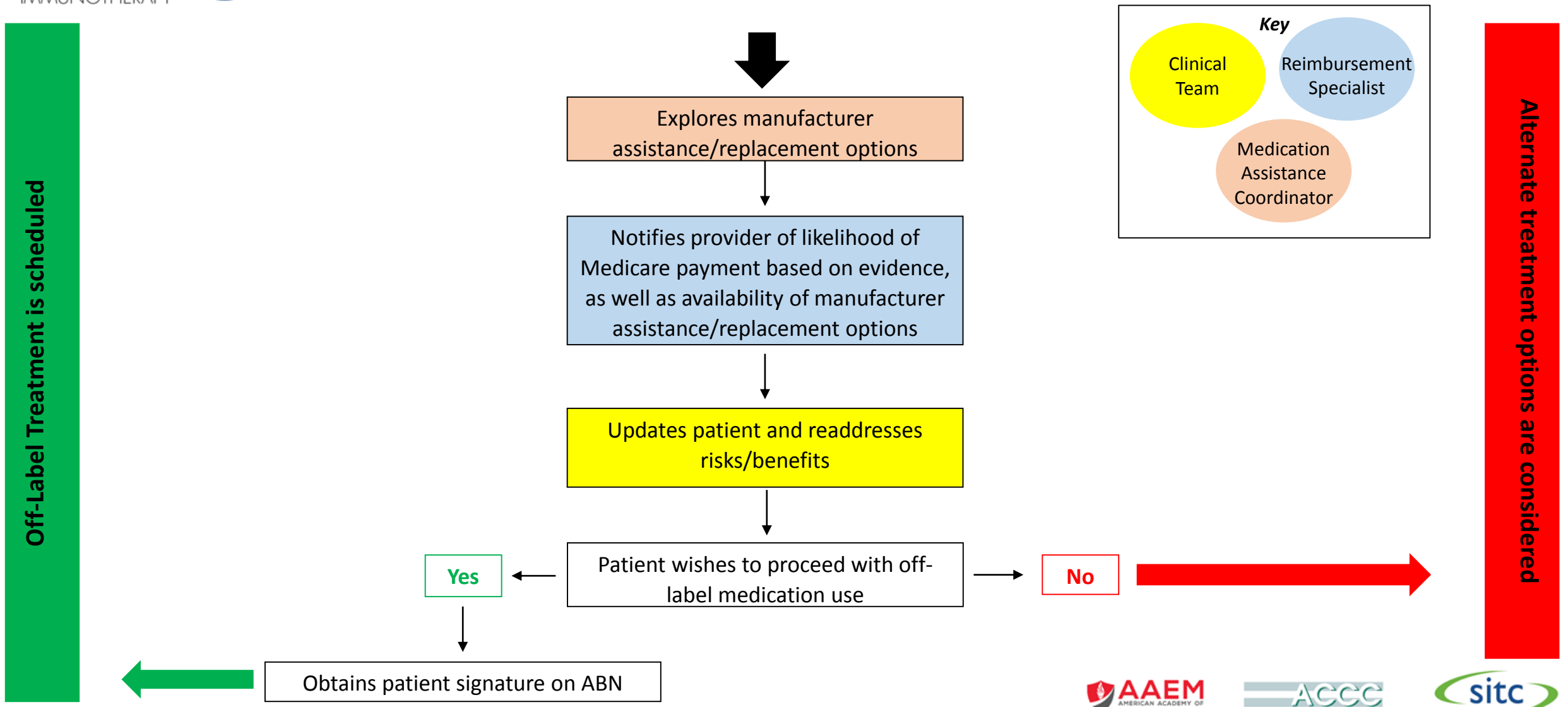
Off-Label Medication Process:

Medicare Pre-Treatment



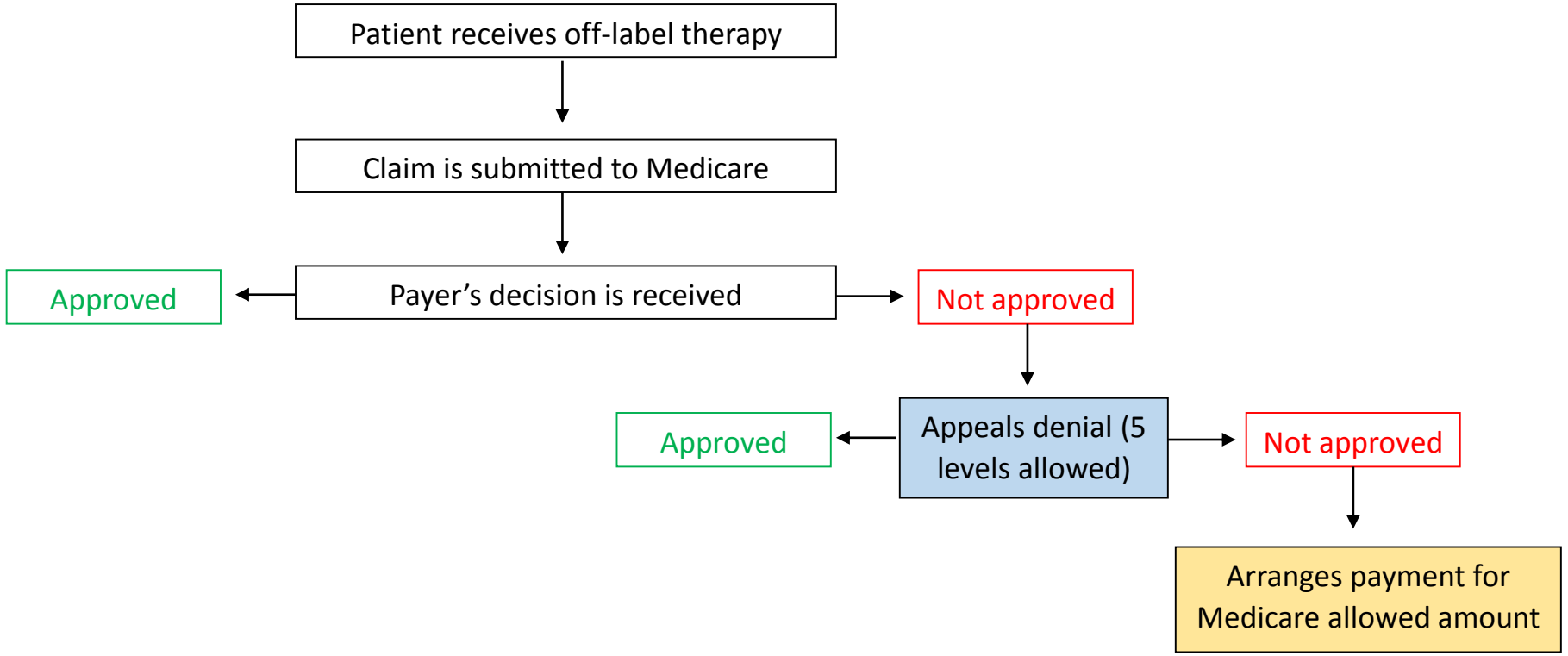
Off-Label Medication Process:

Medicare Pre-Treatment



Off-Label Medication Process:

Medicare Post-Treatment



Key

Clinical Team

Reimbursement Specialist

Medication Assistance Coordinator

Chief Financial Officer

Managed Care

Financial Counseling

Commercial Payers

- Policies primarily based upon published scientific evidence
- Clinical policy guidelines and pathways
  - Vendor Pathways examples: Well Point, New Century Health, AIM
  - Clinical policies examples: Anthem, Aetna, UHC, Cigna, Humana
- Often the clinical policies require medication eligibility restrictions beyond the label and additional criteria to be met in order to assure reimbursement
  - Example: Anthem clinical policy for nivolumab includes patient's current ECOG score 0-2 be met

Commercial Payers

- Use of maximum dosages regardless of weight
  - Maximum allowable units per day and per date span for specialty drugs
- Use of National Drug Code (NDC) units versus CPT/Healthcare Common Procedure Coding System (HCPCS) units creates confusion and concern for underpayment
  - J code represents the amount of drug per billing unit
    - 1 J code per medication
    - J code established by CMS
  - NDC represents the manufacturer and size of the vial
    - 1 NDC code for each vial size for each manufacturer
    - NDC code established by FDA and manufacturer
  - Monitor closely for errors in underpayment

Commercial Payers

- Disproportionate approvals of total billing units versus doses for a specific period of time
  - Example: Authorization for 90mg pembrolizumab for 6 infusions but date range is for nine months- *Make sure that the dates and authorizations match*
- Always pursue authorization/pre-determination for IO's, regardless of whether the therapy is on or off-label
  - Retrospective denials often occur, particularly for off-label uses, even when there was a pre-determination in acceptance of the use

Commercial Payers

- Billing for waste with immuno-oncology agents
  - Proper usage of the JW modifier
    - JW modifier will indicate the amount of waste volume represented
    - I-O agents that are single-use vials or single-use package for unused portion are eligible
    - Multi-dose vials are not eligible (and currently not available)
  - Not all payers will pay for waste or only pay for part
  - Some payers do not allow rounding of doses and do not pay for waste (a lose/lose situation for providers)
  - Proper documentation necessary in the medical record for discarded waste
    - Mandated wastage rationale for any JW lines on Medicare claims on January 1, 2017

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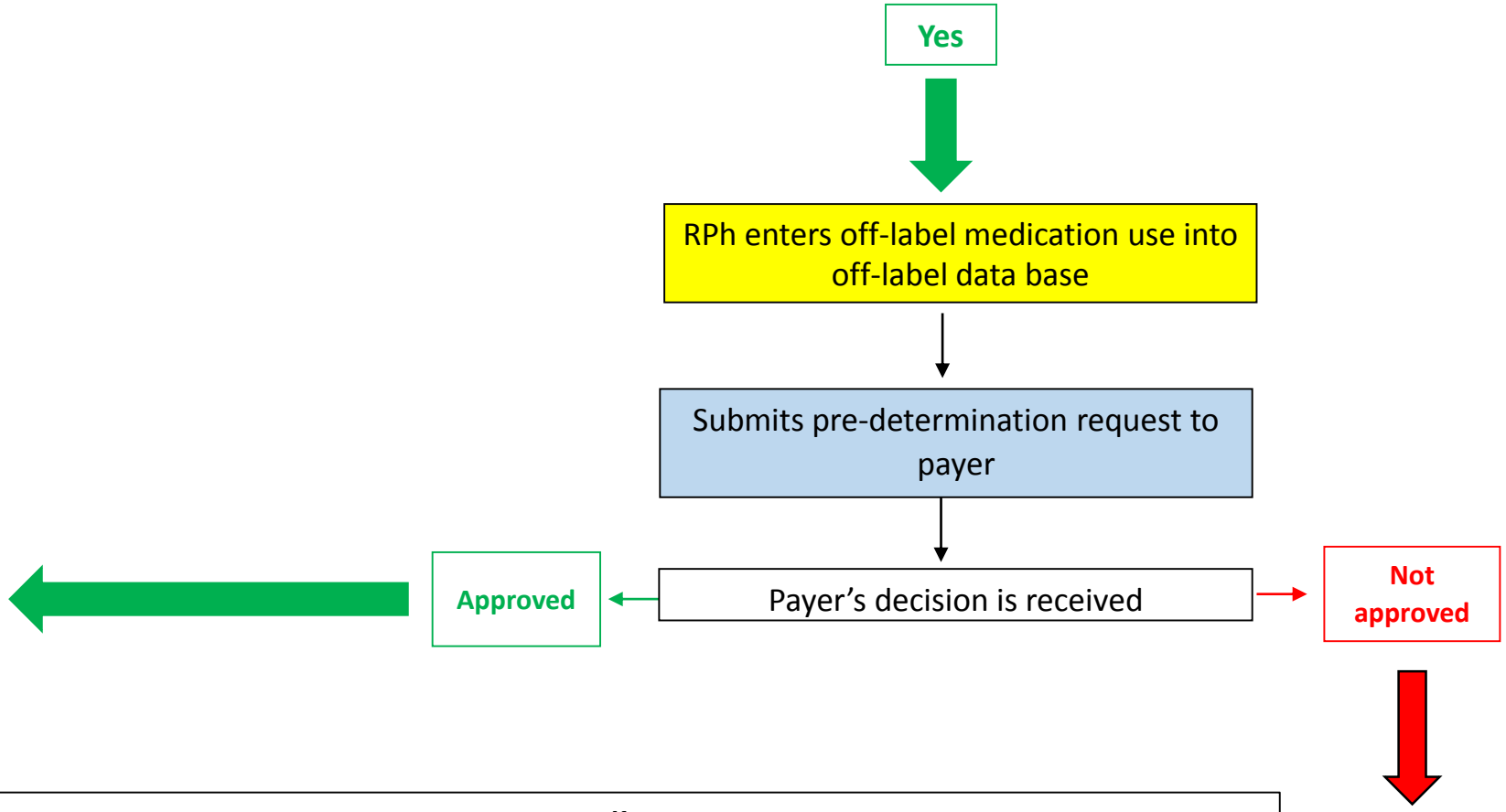

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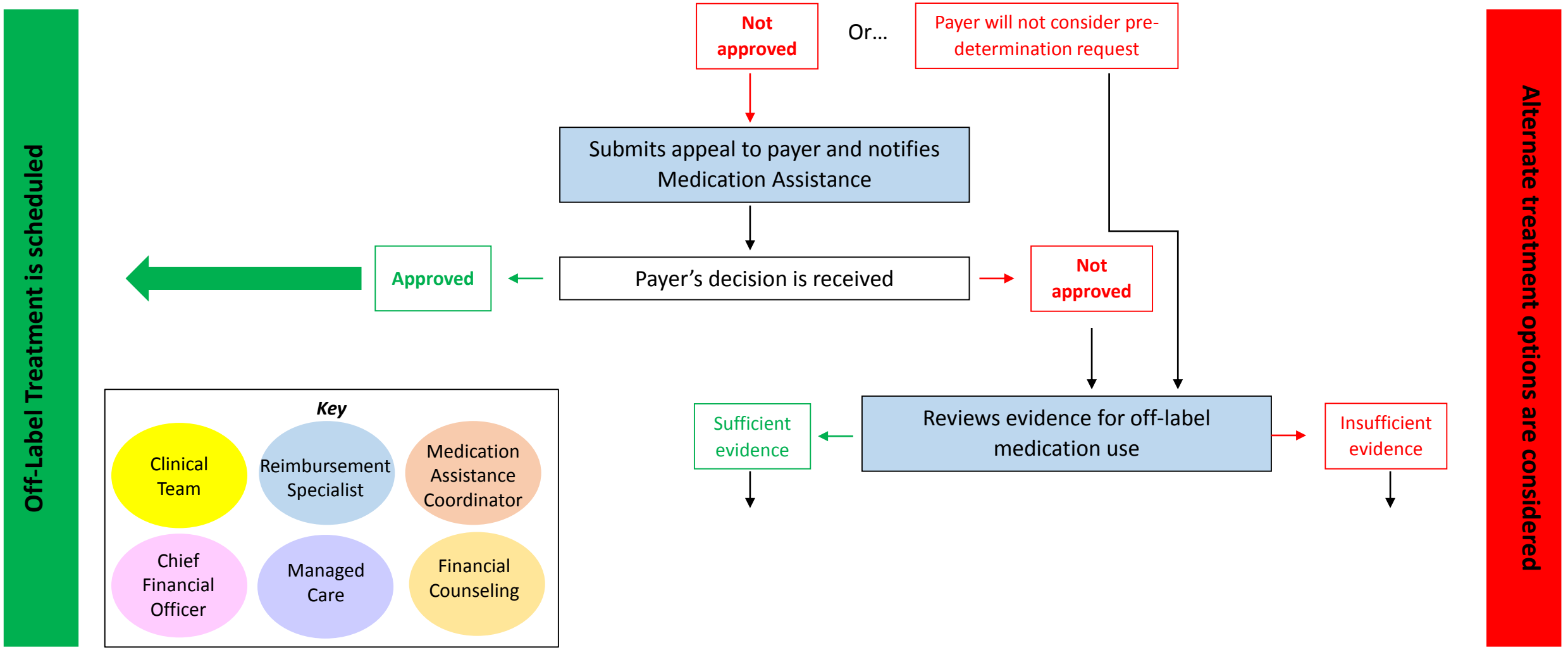

Off-Label Medication Process:
Commercial Payers

Off-Label Treatment is scheduled

Reviews evidence for off-label medication use

- Sufficient evidence
- Insufficient evidence

RPh escalates off-label request to disease-specific leader, division director, and pharmacy director

- **Approved**
  - Notifies provider and Medication Assistance
    - Explores manufacturer assistance/replacement options
    - Updates patient and readdresses risks/benefits
- **Not approved**

Alternate treatment options are considered

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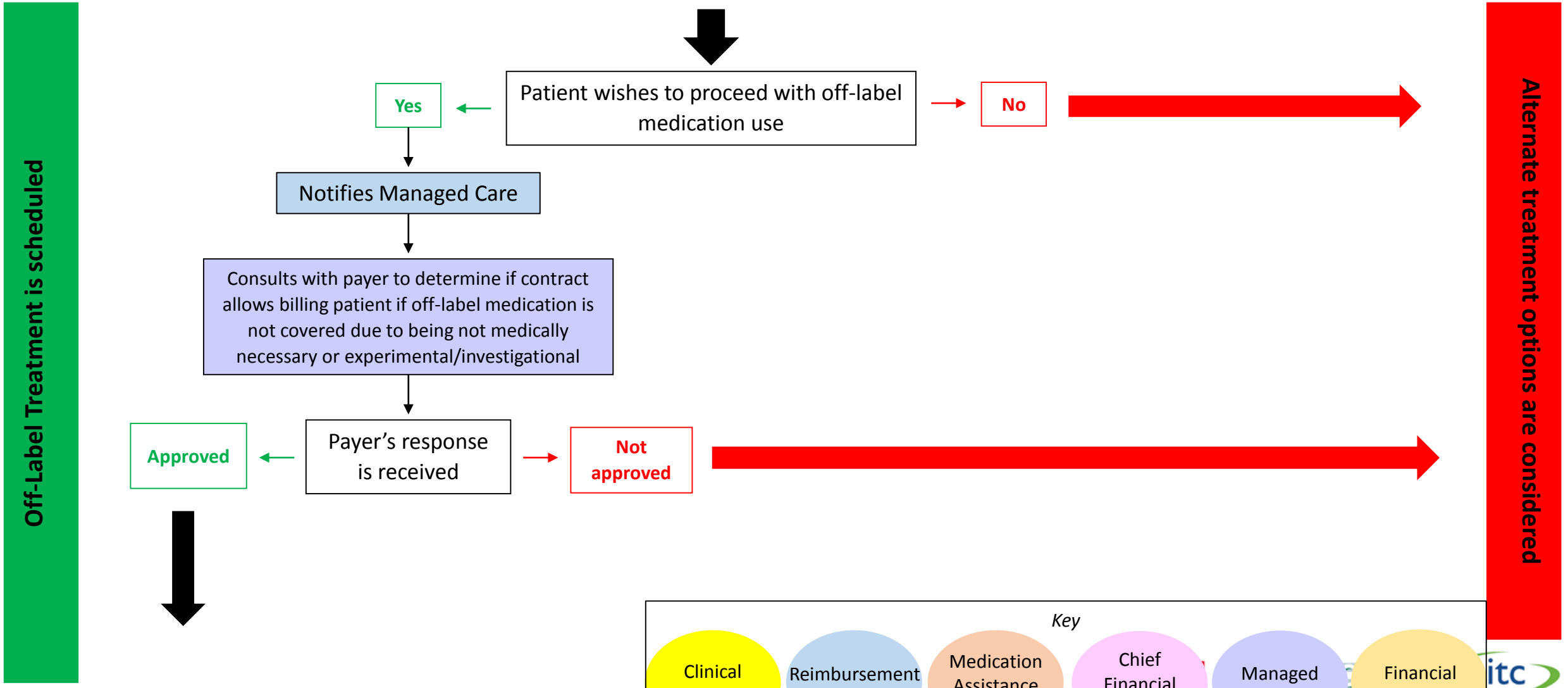


Off-Label Medication Process:
Commercial Payers

Off-Label Treatment is scheduled

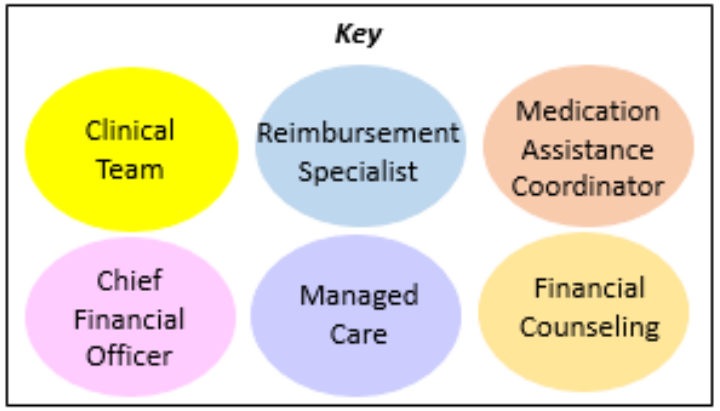
Notifies chief financial officer

Determines appropriate amount for patient to deposit toward treatment costs prior to receiving off-label medication

Notifies provider of deposit amount

Communicates deposit amount to patient and readdresses risks/benefits

Patient wishes to proceed with off-label medication use



Alternate treatment options are considered

Off-Label Medication Process:
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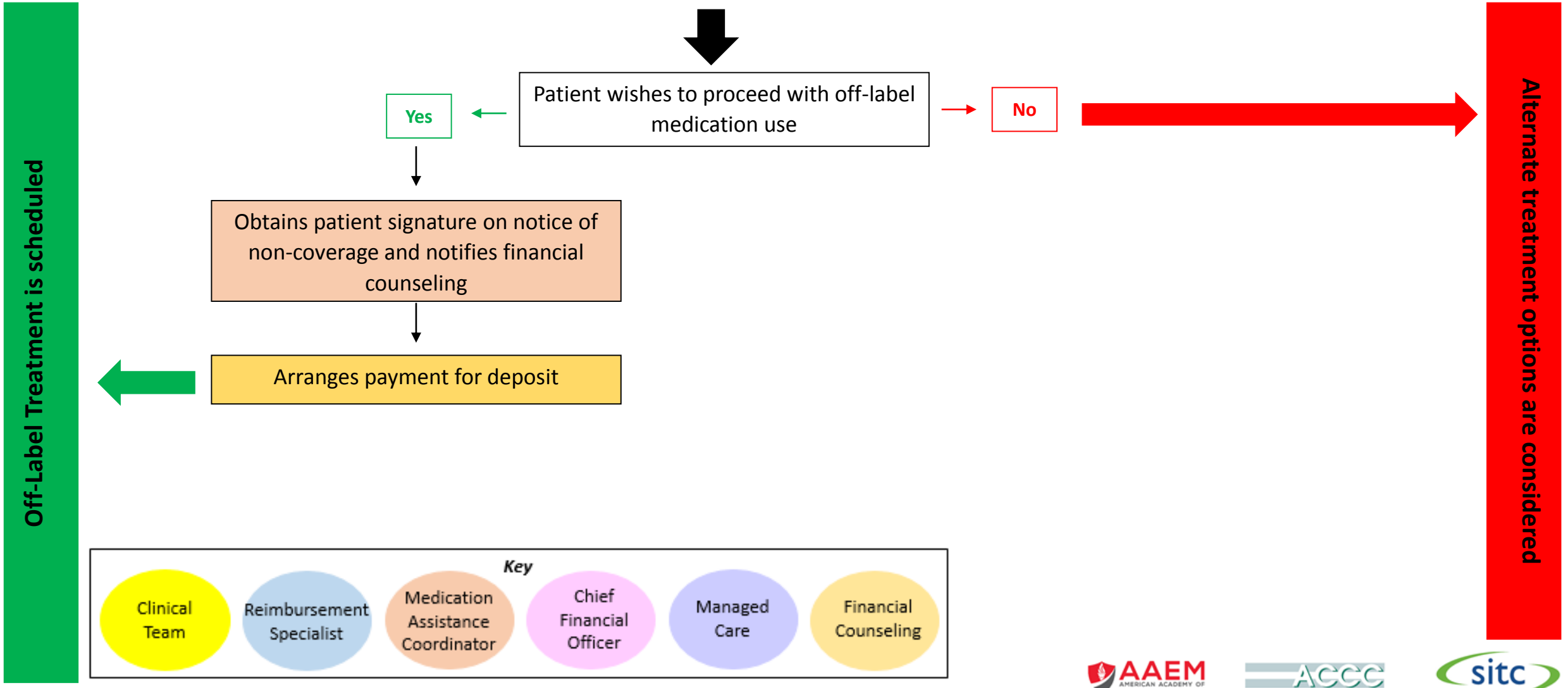


Handling Denials

- Work with Finance to develop a method for routing denials to appropriate personnel
  - Leverage IT to create work queue and notification process
- Consider appropriateness of resources
  - Workload (average number of denials/appeals)
  - Strict appeal timelines of many payers
- Consider training/experience of personnel
  - Ideally a nurse or pharmacist with oncology experience
  - Ability to learn and understand financial systems and processes
  - Ability to navigate electronic medical record

Handling Denials

- Request medical peer to peer interaction
  - Offer additional information and rationale to discuss with clinical reviewers who made initial determination
- Monitor for trends
  - Increased denials for repetitive reasons may require payer, billing or provider education
- Hold payer accountable
  - Regardless of the size of the organization
    - Example: Payer not recognizing authorization because it came from a third party administrator and denying claims for reason of “lack of pre-certification”

Handling Denials

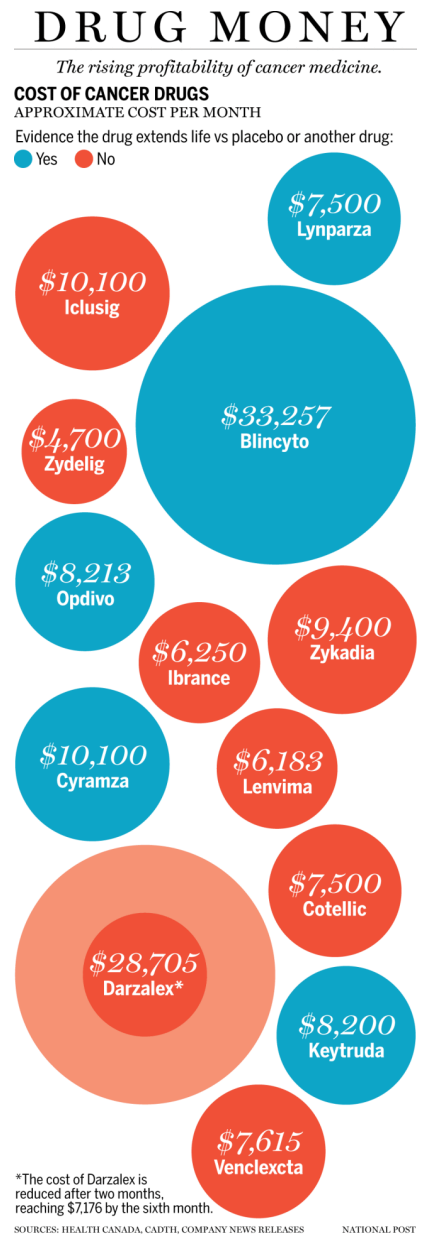
- Challenge outdated payer policies
  - Develop reconsideration packet (for both commercial payer and Medicare) with evidence to support addition of covered diagnoses and/or regimens excluded from payer policies

Canada Considerations

- Drug Access:
  - The best therapeutic option recommended by the oncologist may not be listed on the formulary of the province of residence or by their private insurer.
  - The best therapeutic option recommended by the oncologist may be a take-home medication and the person resides in a province where there is no specific program in place to cover the cost of these medications.
    - Even with private insurance, some patients in this situation will end up having to pay thousands of dollars.
  - The best therapeutic option recommended by the oncologist is in the process of being reviewed by one of the bodies involved in the drug approval process.

Canada Considerations

- Drug Cost
  - Hype versus hope
  - More drugs getting approved based on early phase clinical trials
    - Surrogate endpoints (PFS instead of OS)
  - Cost of managing side effects in addition to cost of the drug
  - Plans placing lifetime or annual caps on what they will cover
  - Unique ability for CADTH (pCODR) to negotiate pricing



T.Blackwell, *Drug Money*, National Post 2019.

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)
- Potential for coverage policies to be biomarker driven (e.g., PDL1 overexpression)
- Financial implications of agents becoming first line
- Management of immune related adverse events