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

Society for Immunotherapy of Cancer

Disclosures

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

- Consultant
  - Castle Biosciences Inc.
  - ACCC
  - Novartis
- Speakers Bureau
  - Merck

- Contracted Research
  - Bristol Meyers Squibb

IO Pipeline and Research

- Current products on the market are the “tip of the iceberg”
- New Immuno-Oncology (IO) product or indication can be expected every few months
- Not only new products, but a myriad of new combinations and regimens
- Now over 1,300 IO clinical trials available (clinicaltrials.gov)
- Examine pipeline reports published by pharmaceutical companies

Strategies for Disseminating New Information

Immuno-Oncology Champion

- Identify an “Immuno-Oncology Champion” to be the “I-O point person” responsible for product questions and staff education (physician, advance practice nurse of pharmacists)

Patient Education

- 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 (**wallet cards**, brochures, educational videos)

Staff Education

- Proactively update staff on new information and consider use of manufacturer-provided resources 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 Identification

- Educate patients to clearly identify themselves receiving or having received IO therapy
- Implement medical record identification for those receiving IO therapy

Staff Education

- Ensure staff understands and can identify the common adverse events associated with I-O products
- Know when these events could be potentially be life-threatening and/or require immediate clinical attention

Develop Approval Process

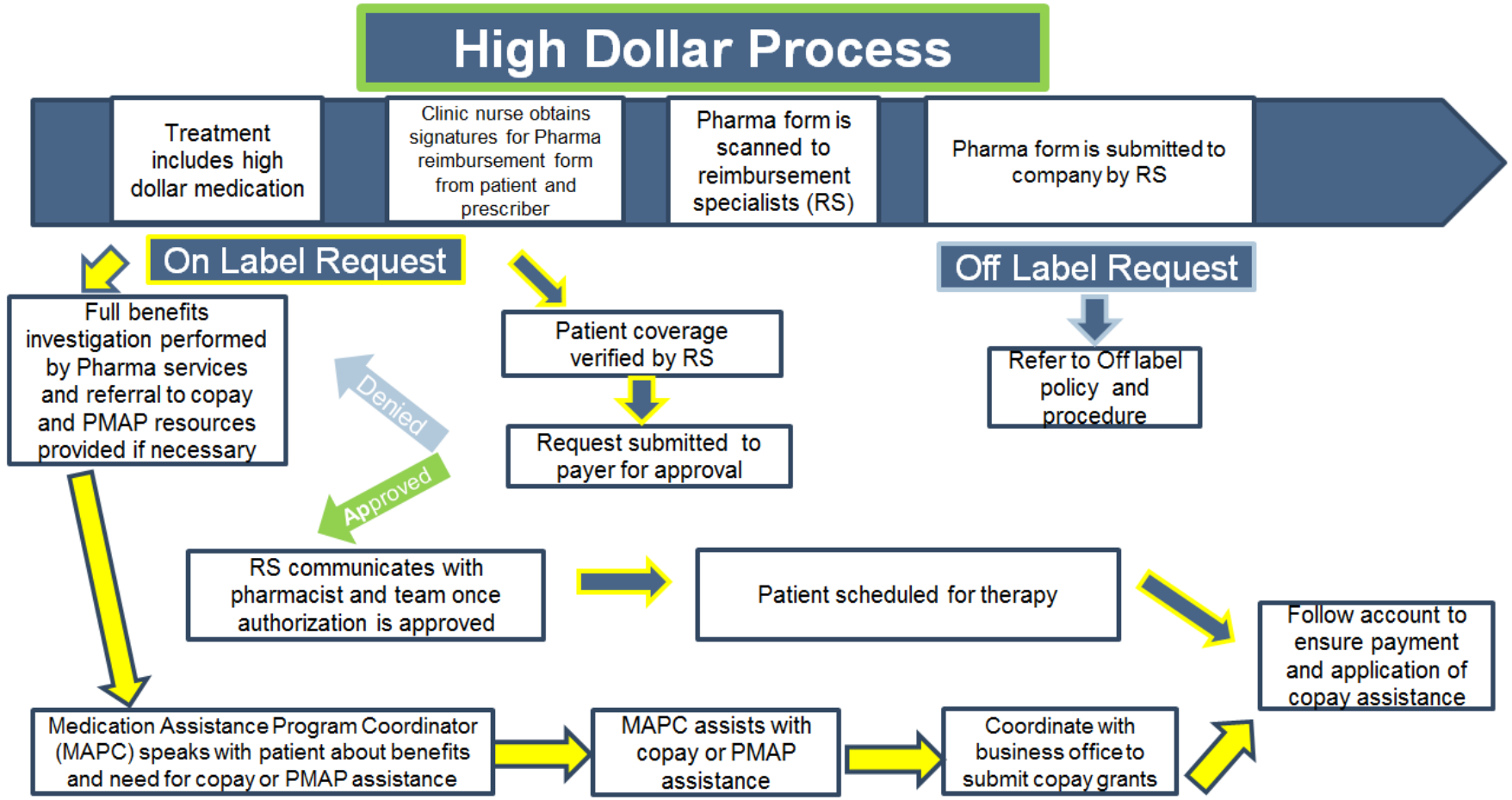
High Dollar Medication Approval Process

- Full benefits investigation, utilize pharma services if offered and allowed per hospital/institution policy
- Prioritize staff resources to enroll every eligible patient into a support program, regardless of on or off-label drug usage

Robust Off-Label Policy and Procedure

- All off-label requests require predetermination
- Make patients aware of risks and benefits, including financial risk
- Patients are required to sign an ABN (Advanced Beneficiary Notice) or NONC (Notice of Non-Coverage)
- Peer review process for appeal if needed

High Dollar Process



Manage Reimbursement

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 benefit verification programs, replacement programs, co-pay support programs, co-pay foundations, and patient assistance programs

Ensure 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.

Medication Assistance

Copay Assistance

Commercial

- Manufacturer may provide up to $25,000 assistance

Medicare

- Not eligible for manufacturer assistance
- Patient may have $4,000 - $6,700 out of pocket responsibility
- Consider foundation support ($15,000 - $25,000 if within 400% of poverty level)

Consider free drug or replacement program direct from manufacturer for denials and off-label therapy – Requires appropriate financial counseling and medication assistance coordinator support

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
  - CMS 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

↓

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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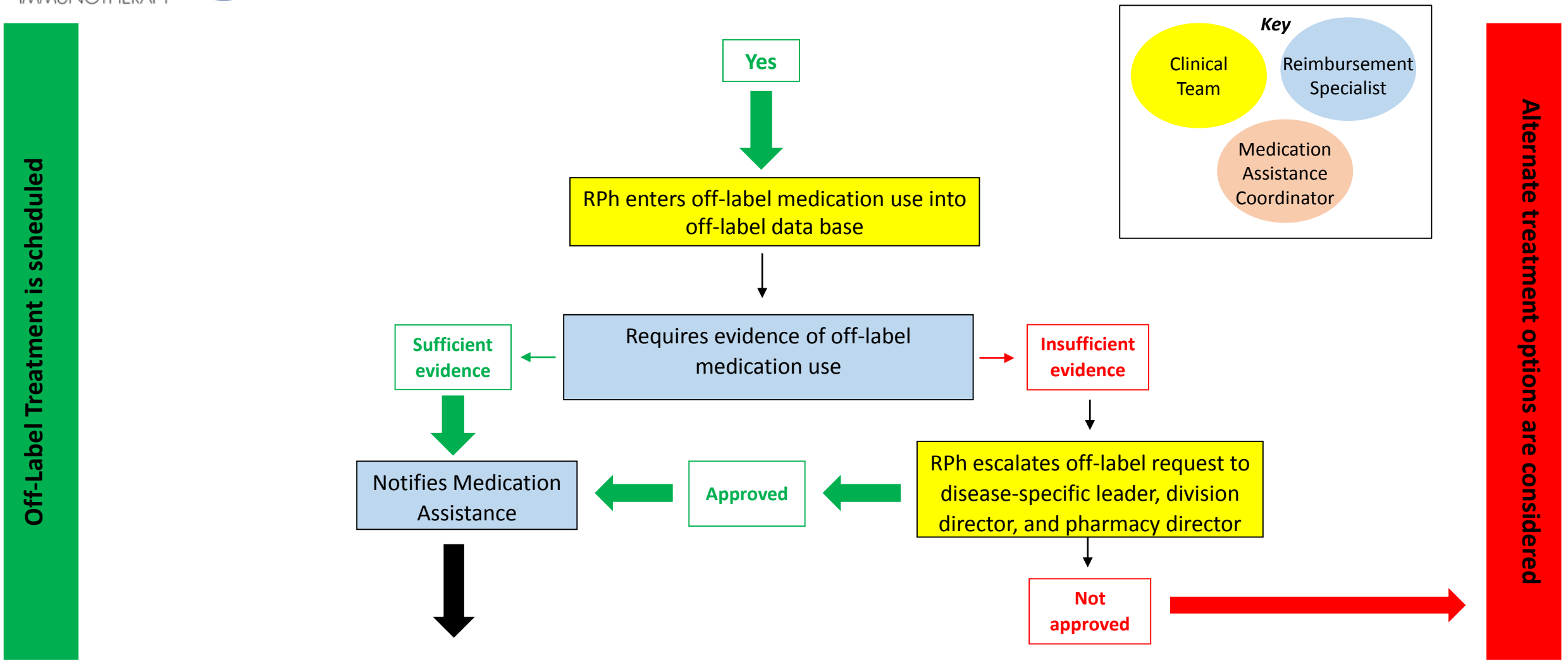
Key

- Clinical Team
- Reimbursement Specialist
- Medication Assistance Coordinator

Off-Label Medication Process:

Medicare Pre-Treatment



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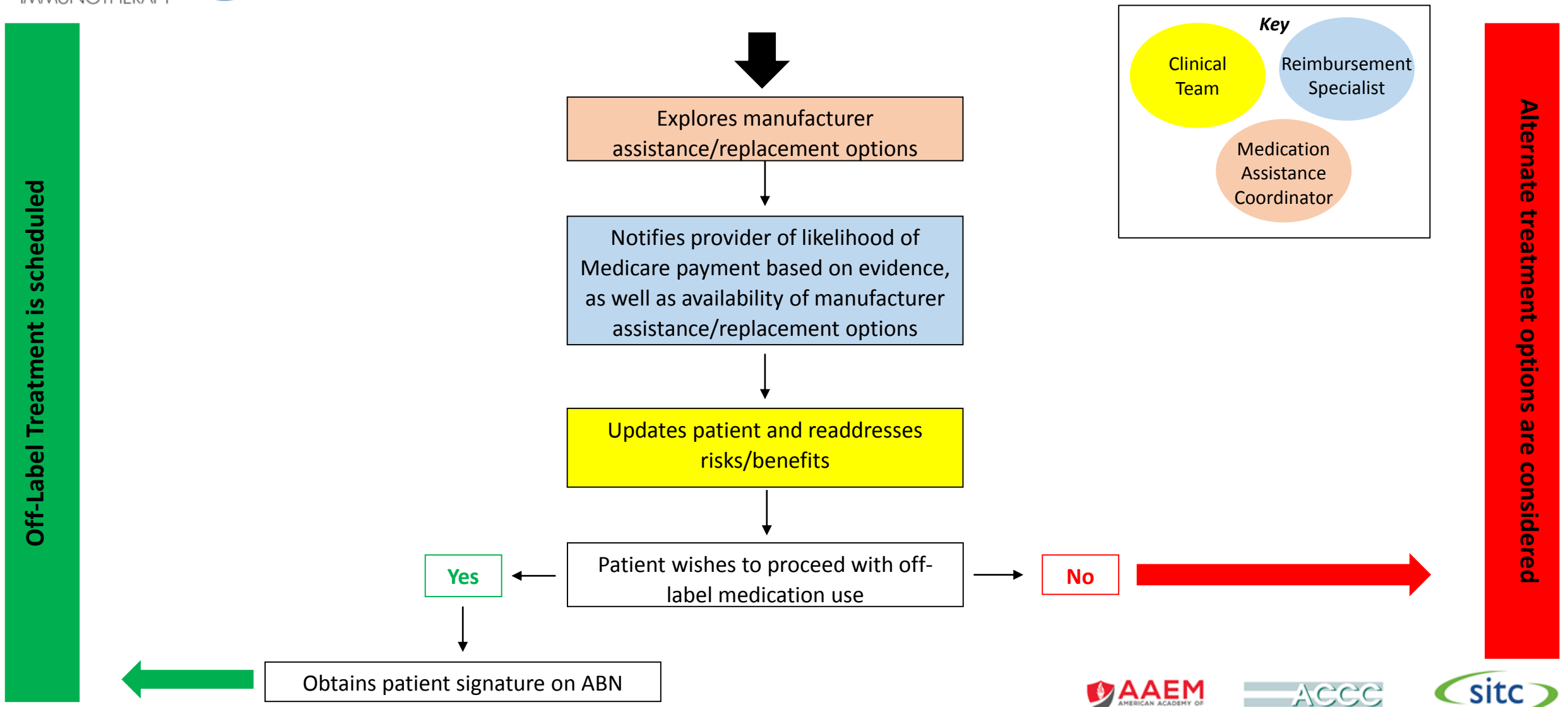
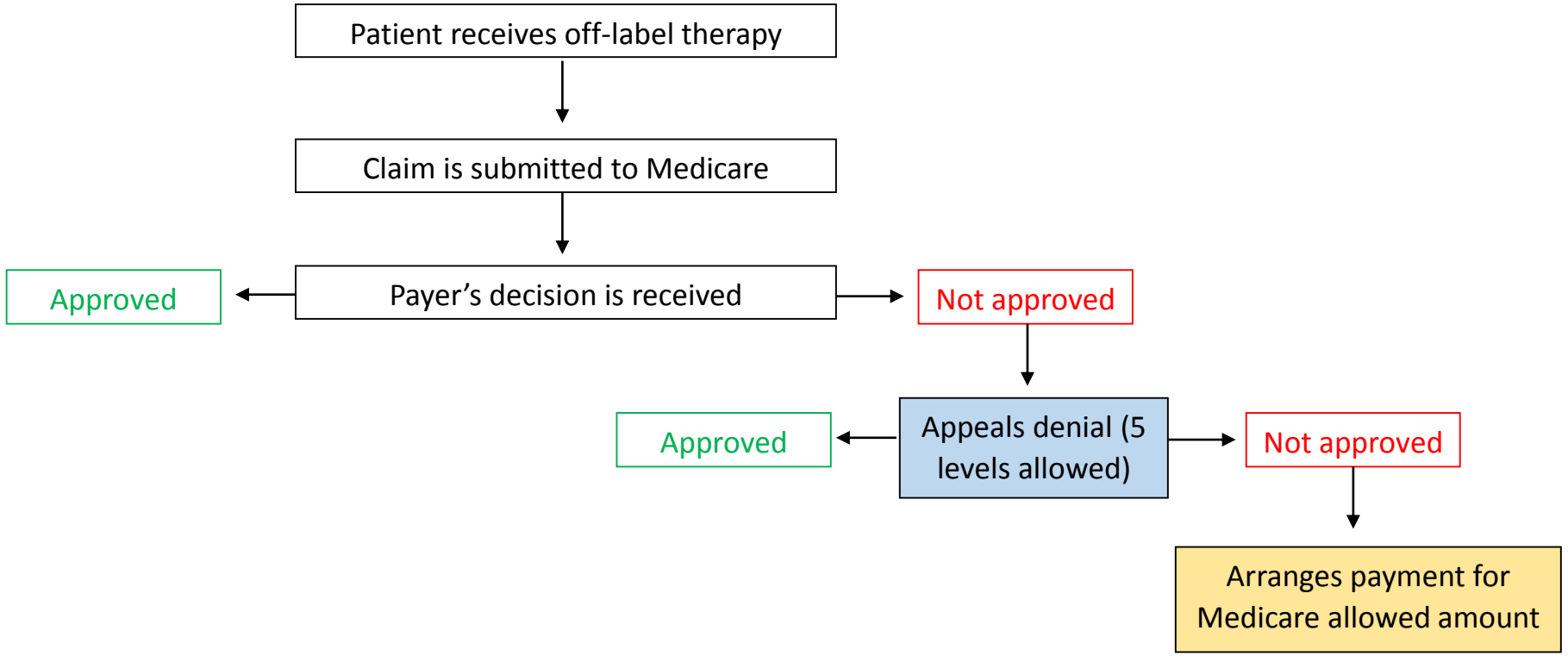
Medicare Pre-Treatment



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 clinical policies recommend medication eligibility restrictions beyond the label with additional criteria to be met in order to ensure 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 90 mg pembrolizumab for 6 infusions but date range covers 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

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 are eligible unused billing
  - 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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Commercial Payers

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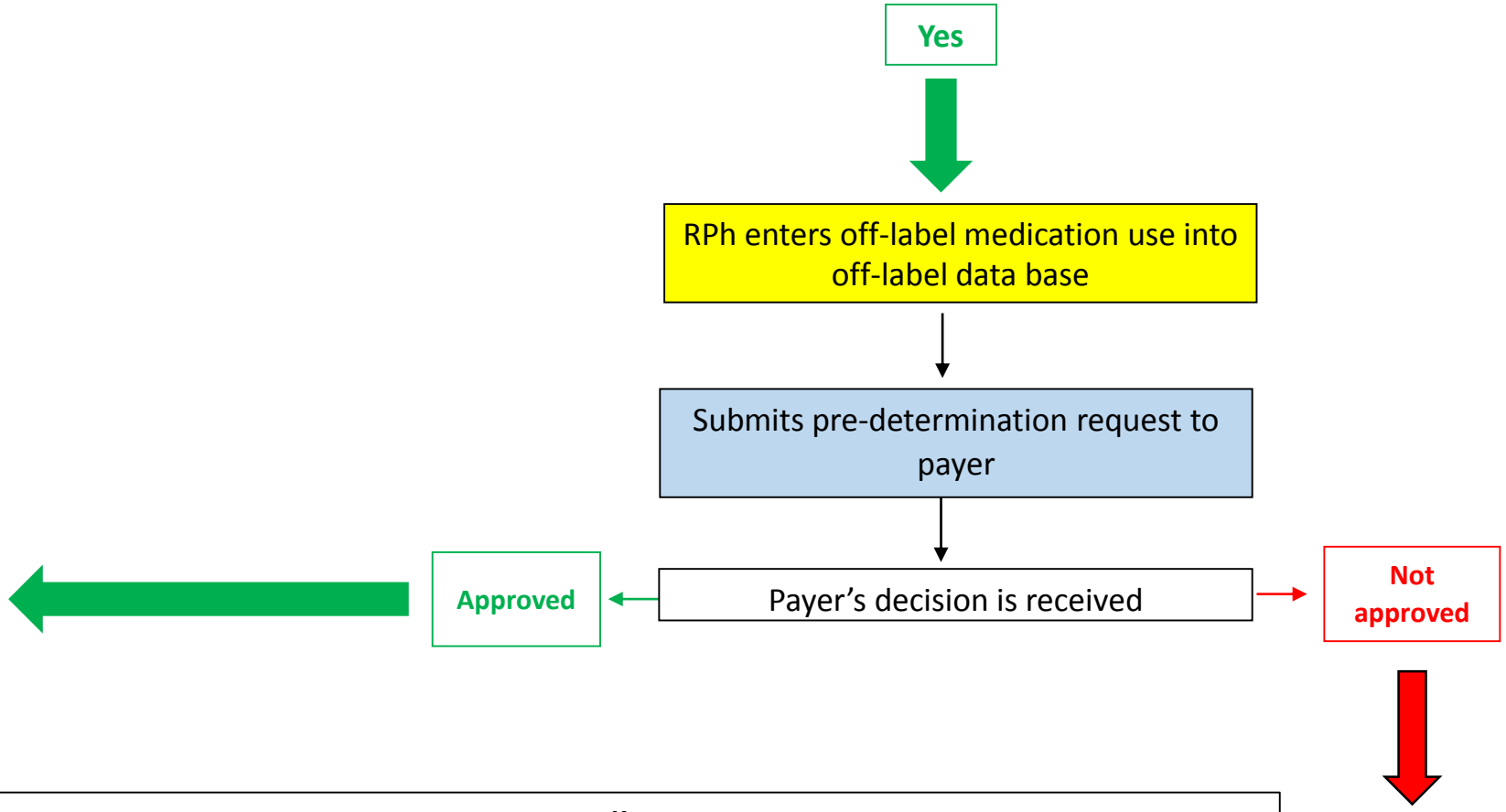

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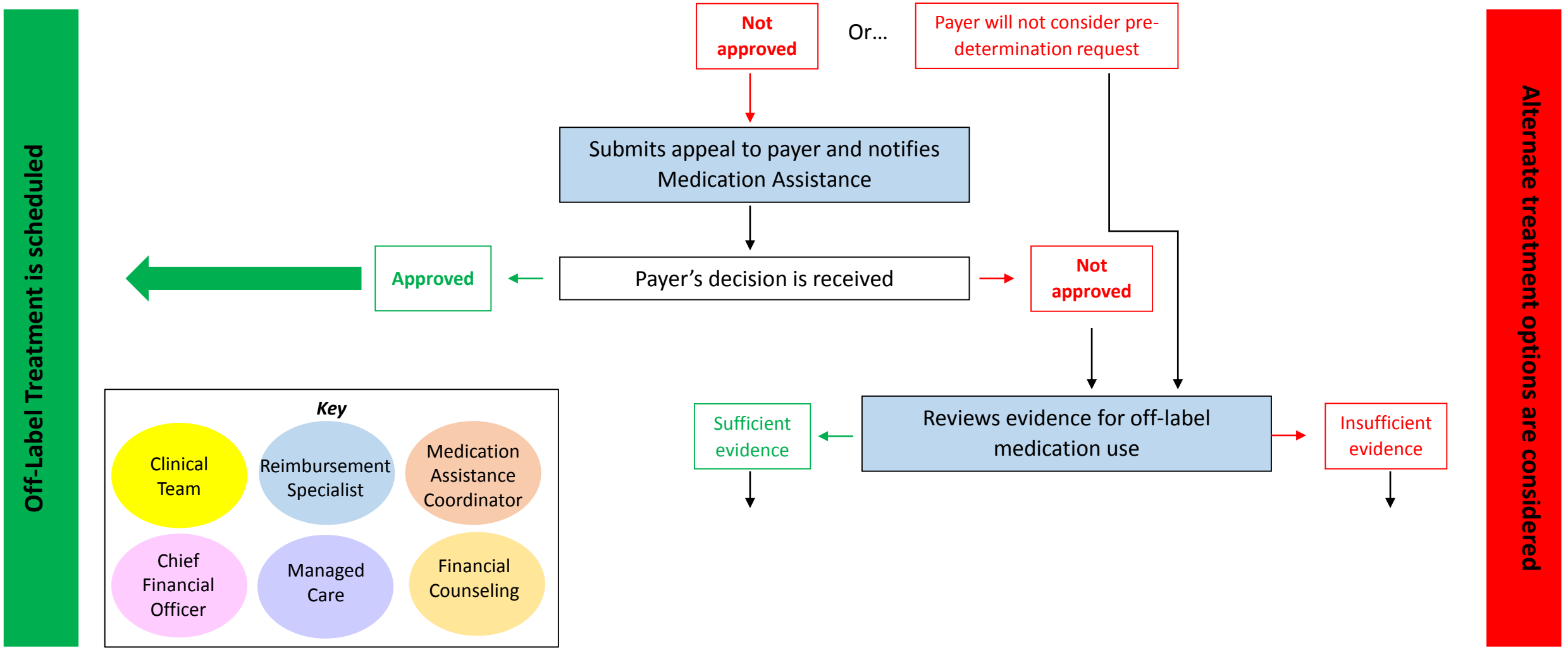

Off-Label Medication Process:
Commercial Payers

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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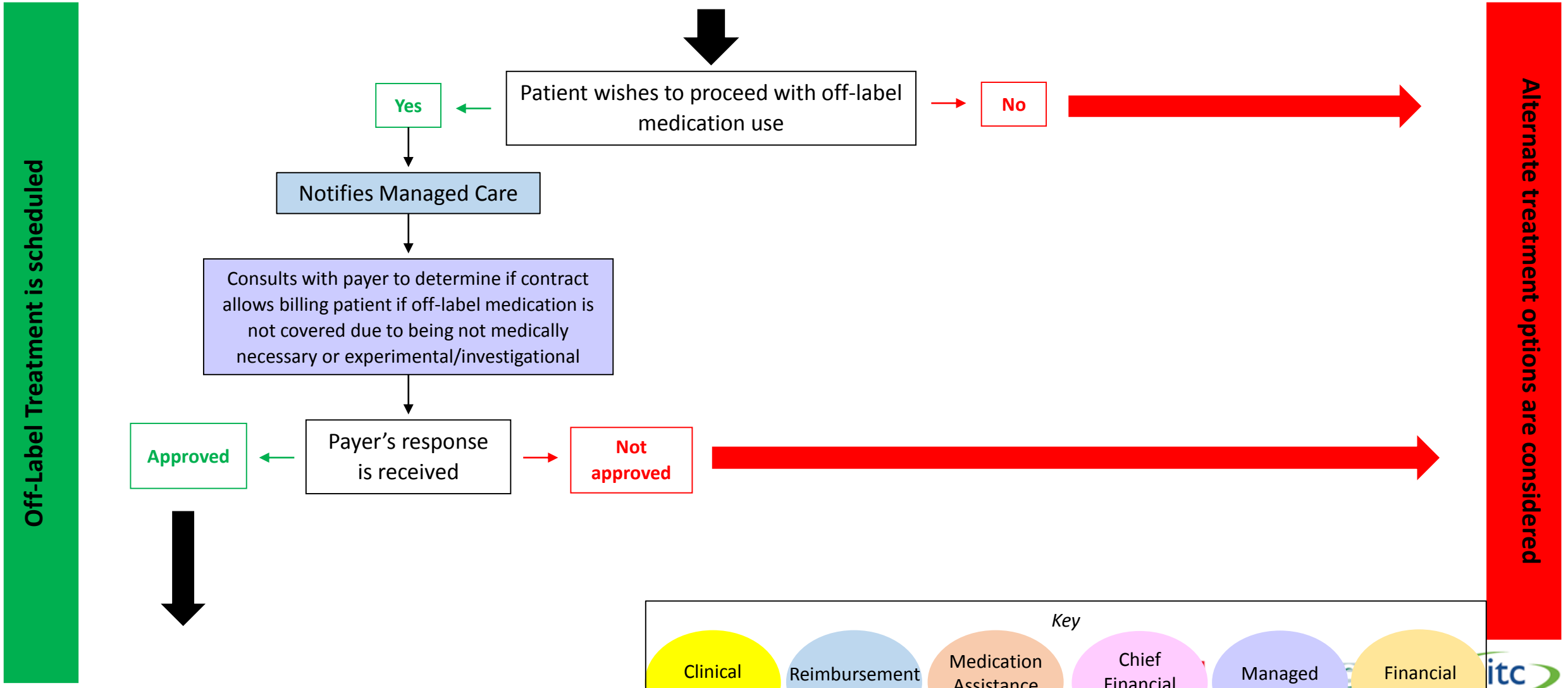


Off-Label Medication Process:
Commercial Payers

Off-Label Treatment is scheduled

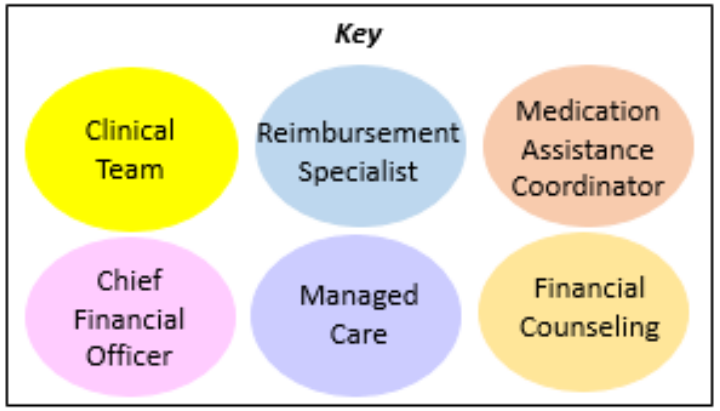
Notifies chief financial officer

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



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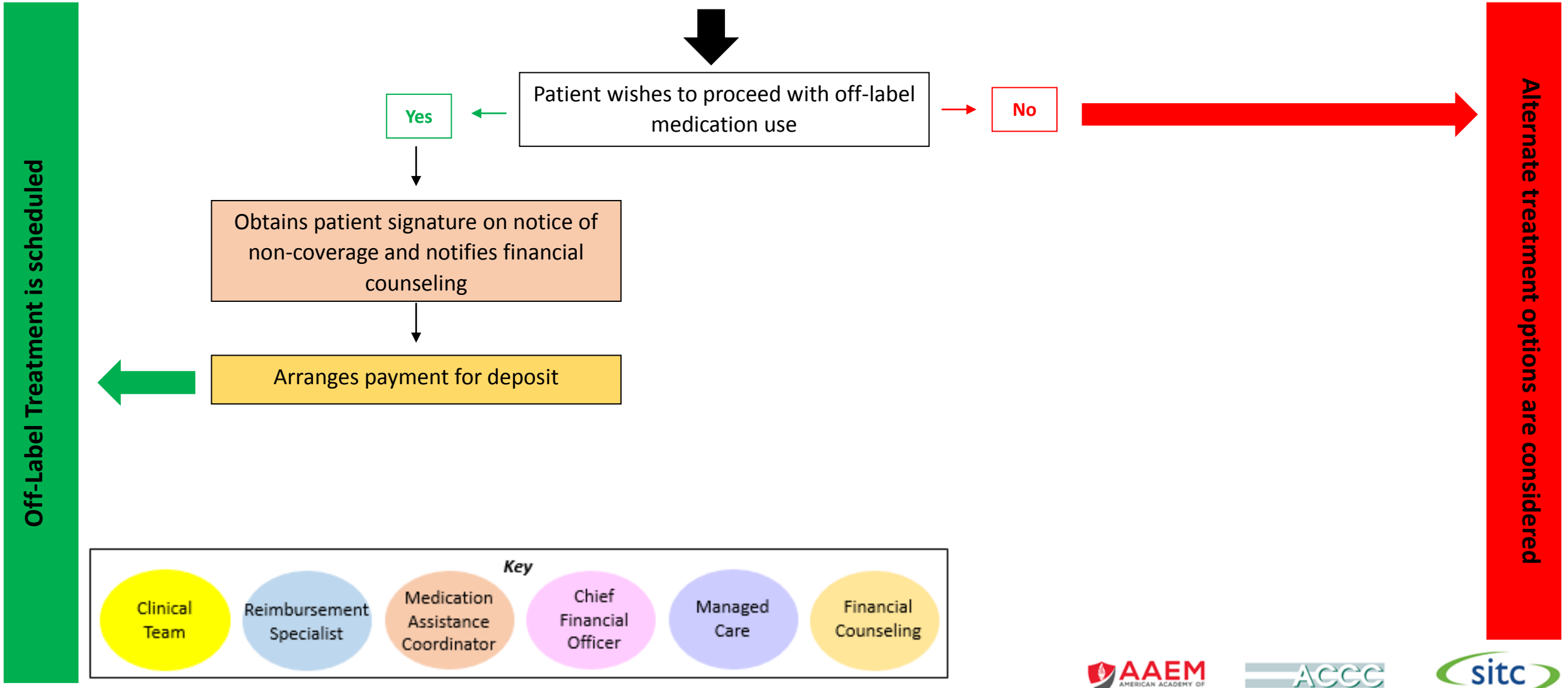

Common Reasons for Denials

- Lack of pre-certification or authorization
- Medical necessity
- Experimental and investigational agent
- Additional information Required
- Non-covered service/medication on the plan benefit
- Out of network provider
- Time to claim filing
- Multiple diagnoses for disease states and metastases- payer does not apply correct codes to medications
- Error in number of units billed to payer
- Insurance duplicity or delay

General Rules for Denials

Discover the root cause of the denial

- Review payer specific policy, LCD, NCD
- Determine if pre-certification or prior authorization was completed
- Review documentation
  - Reimbursement is linked to the quality of the bill
  - Coders obtain information from medical record but sometimes required information is missing

Look for denial trends with payers

- Drugs, diagnosis, charge threshold

Exceeds total units allowable

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

Future Considerations

Be mindful of payers ability to keep up with accelerating evidence based indications (e.g., new lines of therapy, new tumor type indications)

Increasing utilization of I-O agents in combination with a host of drugs (e.g., chemo, targeted, immunotherapeutic)

Potential for coverage policies to be biomarker driven (e.g., PDL1 expression, TMB)

Financial implications of agents becoming first line