

Practical Barriers in Cancer Immunotherapy Treatment

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Disclosures

- Consulting Fees: BMS, Merck, Pfizer
- Fees for Non-CME/CE Services Received Directly from a Commercial Interest *or their Agents*: BMS, Cardinal Health
- I will 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 or 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 resources including on-site training/education

Emergency Response

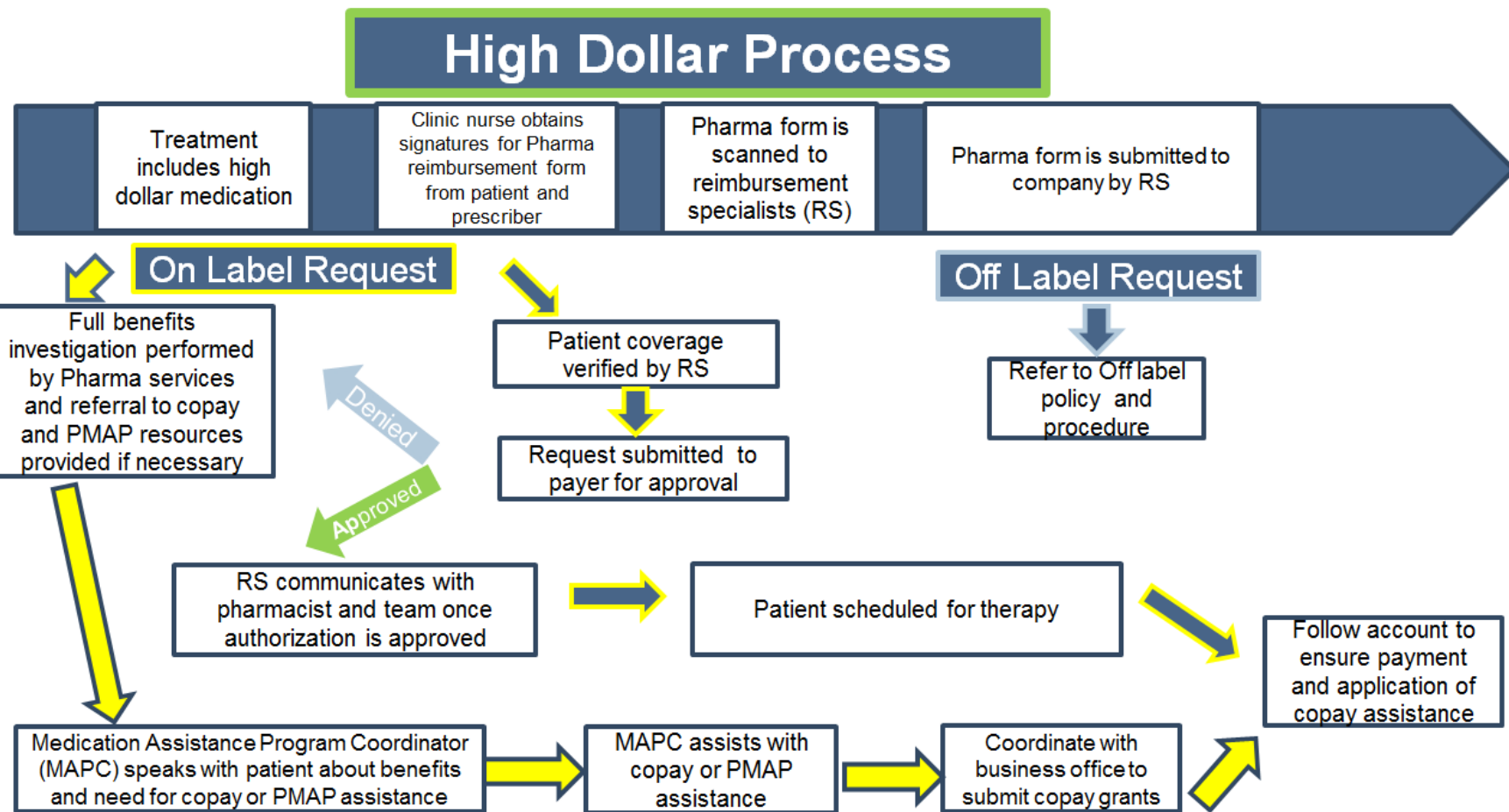
- Develop protocols
 - Use your “I-O Champion” to take the lead in developing/revising any treatment protocols that may be impacted by the addition of new I-O therapies in your practice
- Patient education
 - Educate all patients on an I-O therapy to clearly identify themselves as such; make sure that 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

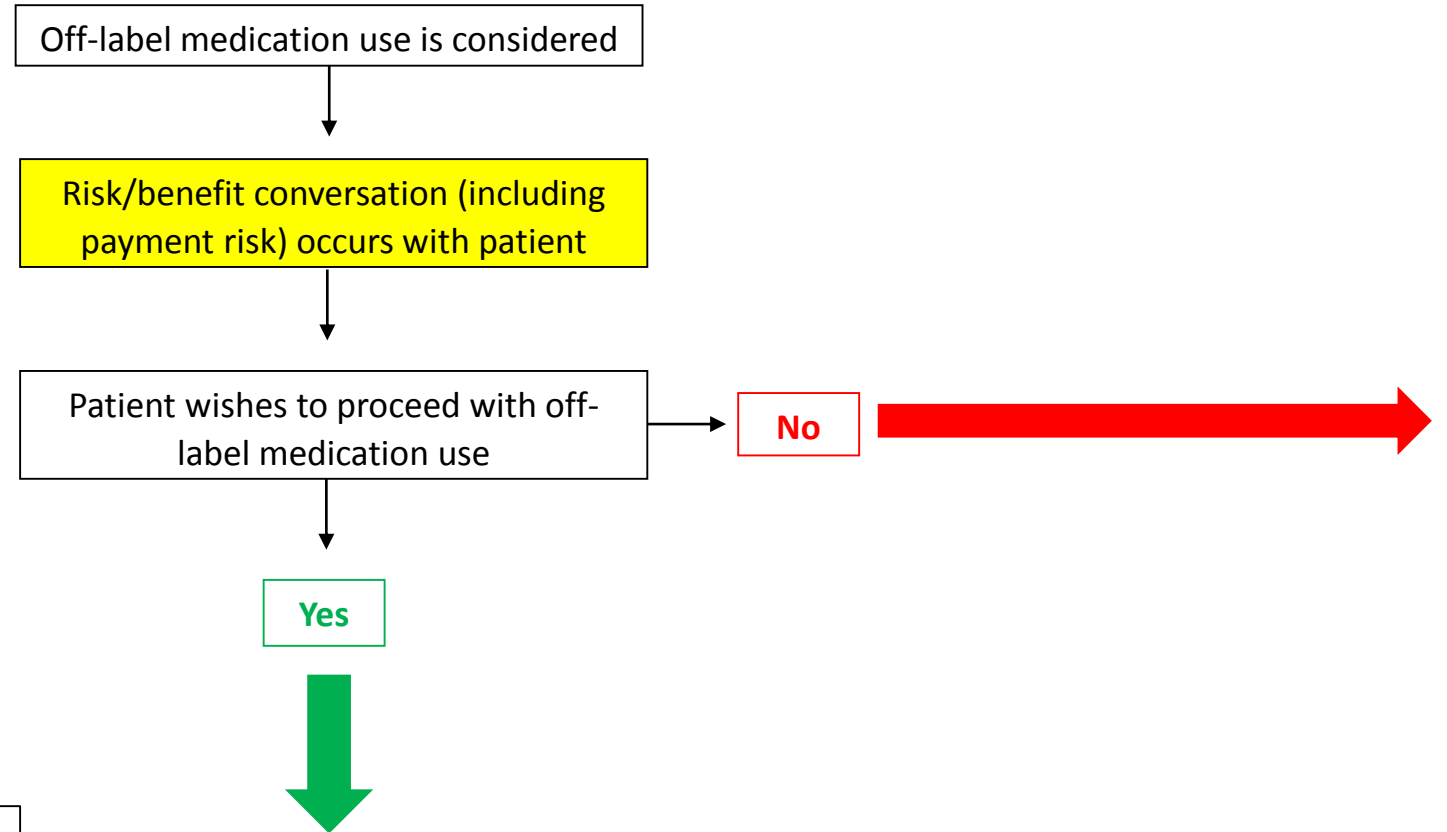


Medicare

- 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



Alternate treatment options are considered

Key

Clinical Team

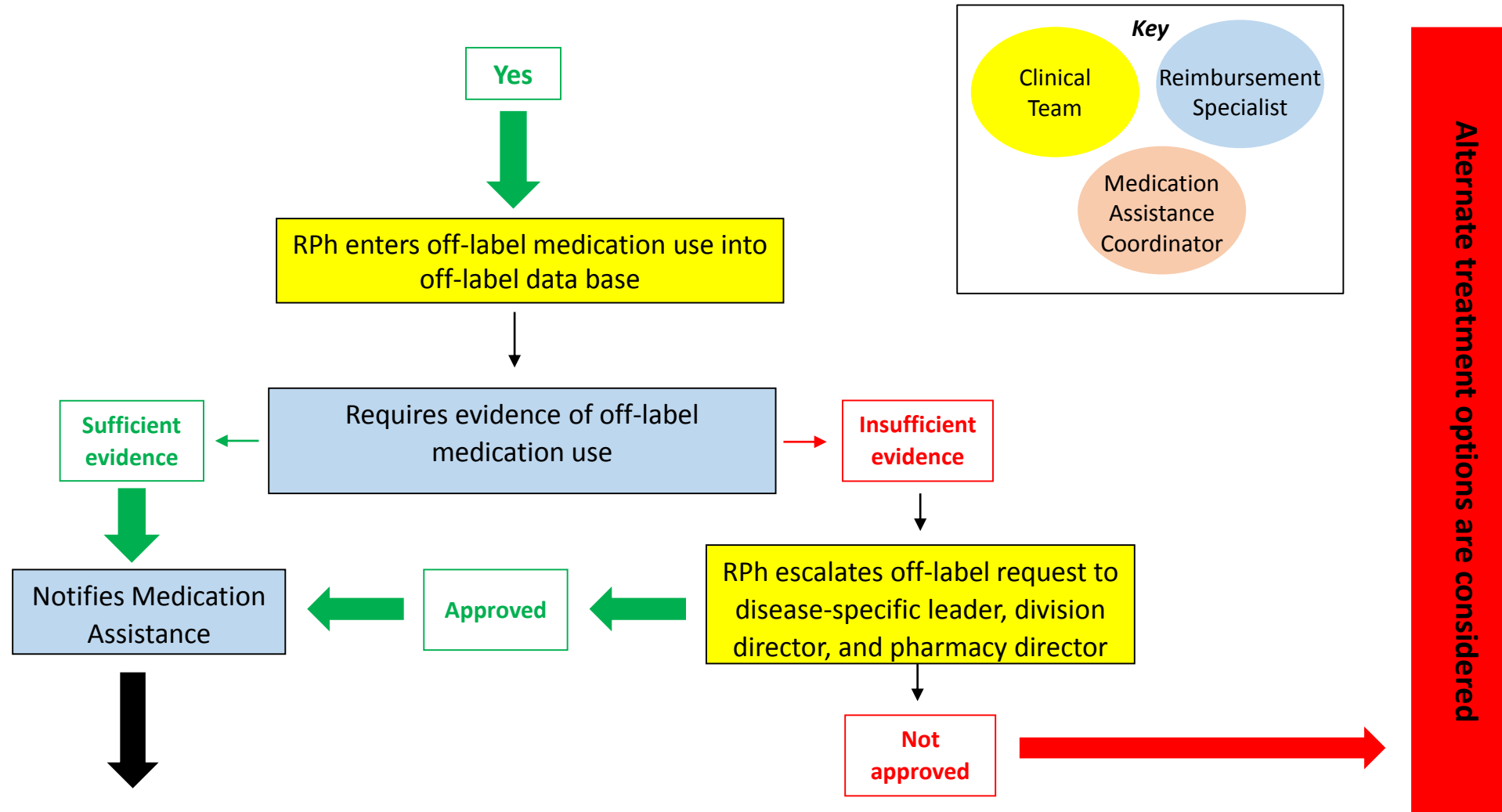
Reimbursement Specialist

Medication Assistance Coordinator

Off-Label Medication Process:

Medicare Pre-Treatment

Off-Label Treatment is scheduled

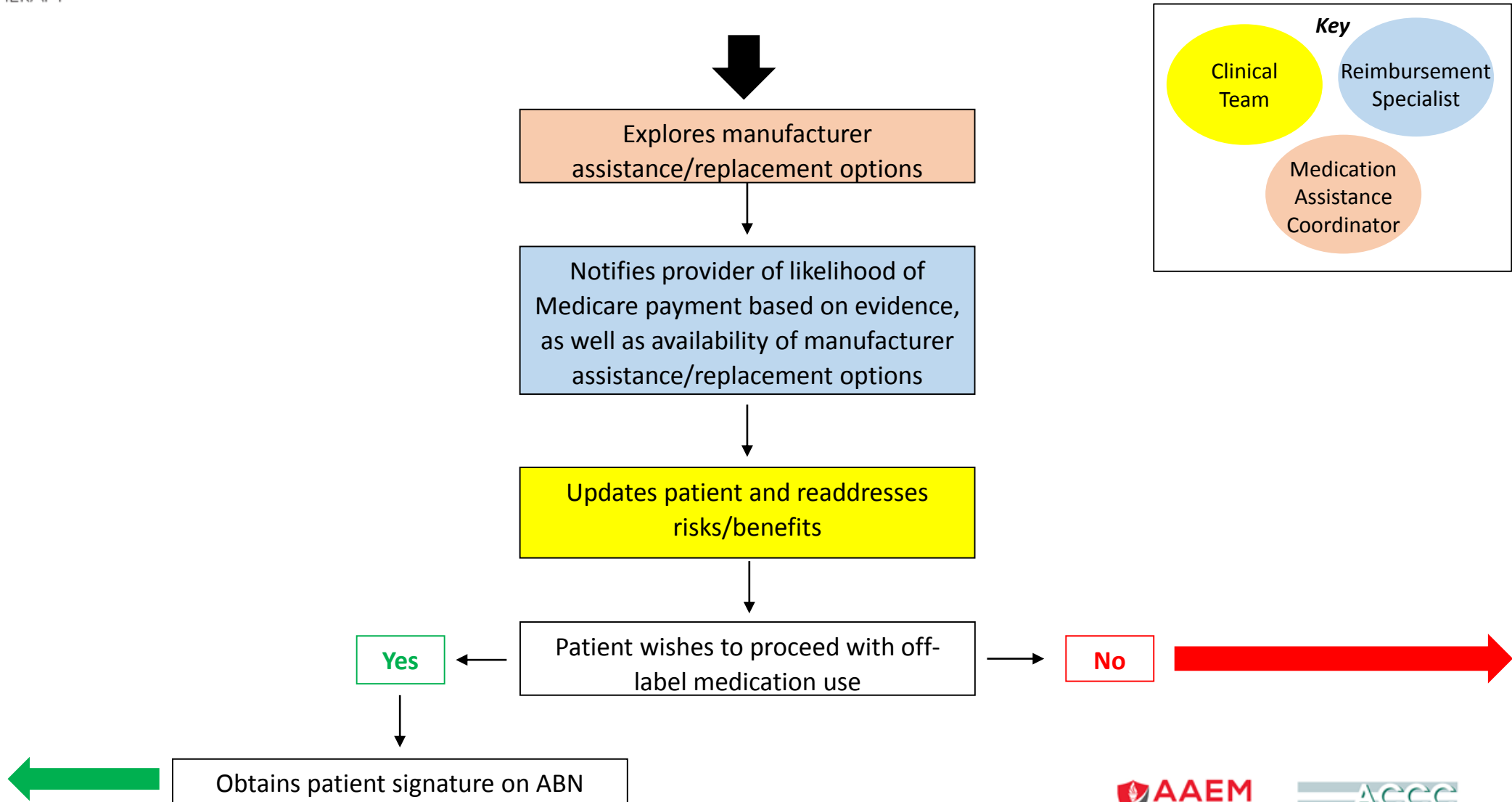


Off-Label Medication Process:

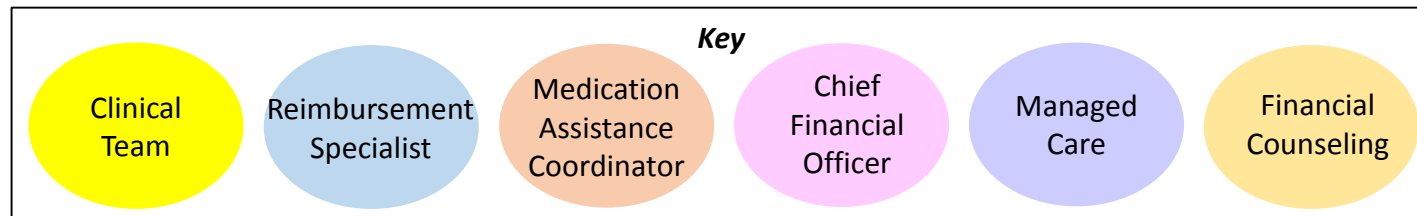
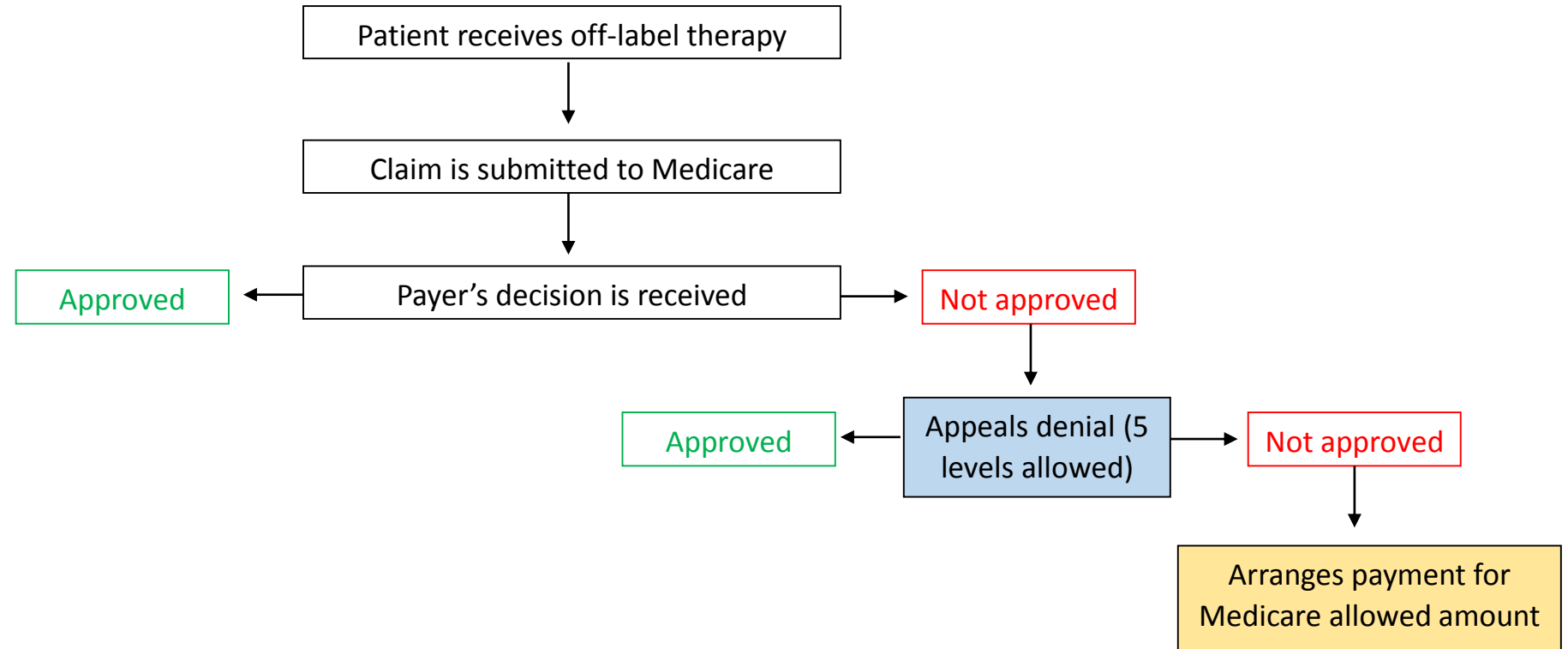
Medicare Pre-Treatment

Off-Label Treatment is scheduled

Alternate treatment options are considered



Off-Label Medication Process: *Medicare Post-Treatment*



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

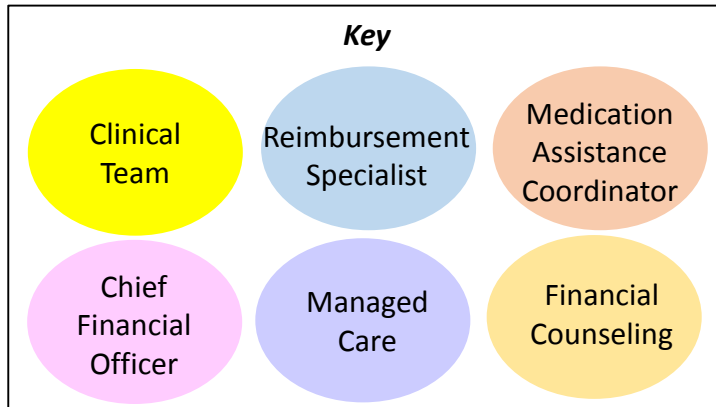
Commercial Payers

- 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

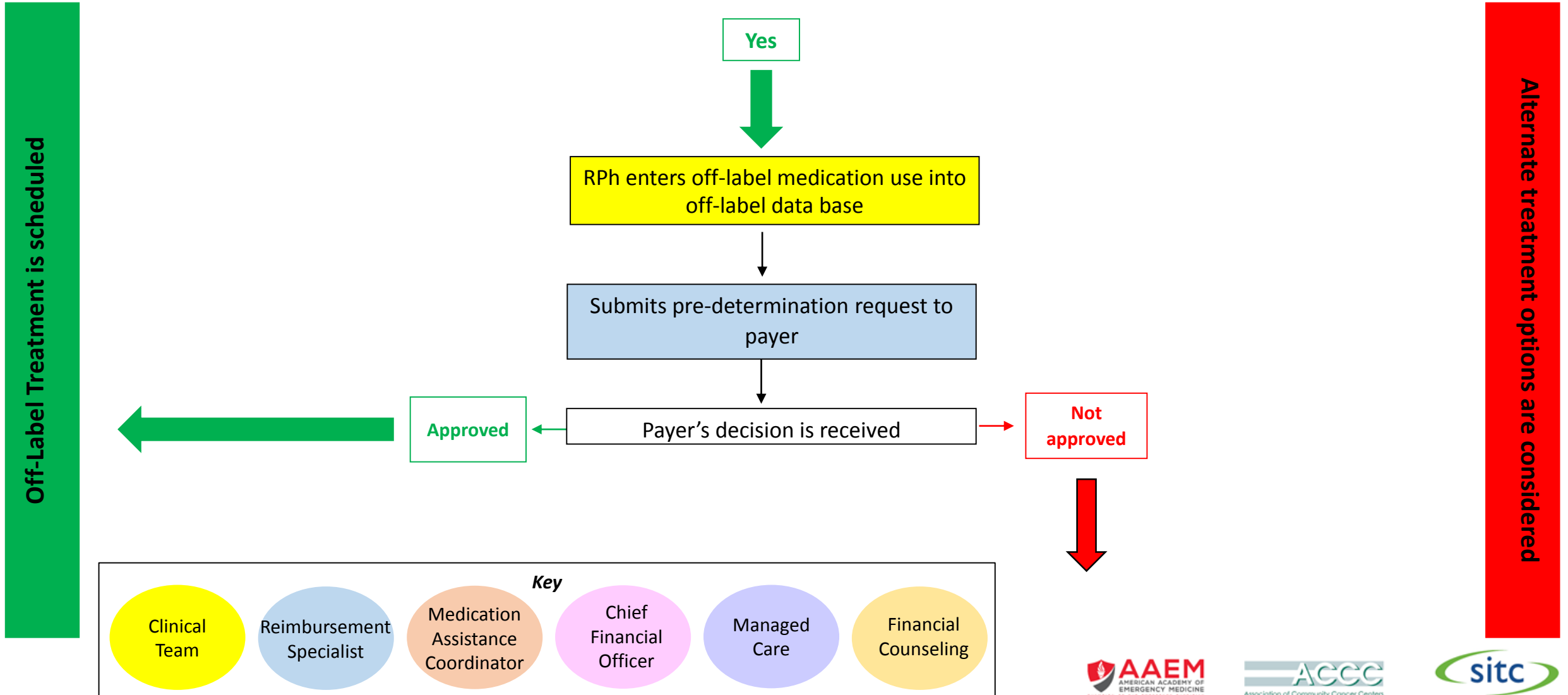
Commercial Payers

- 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

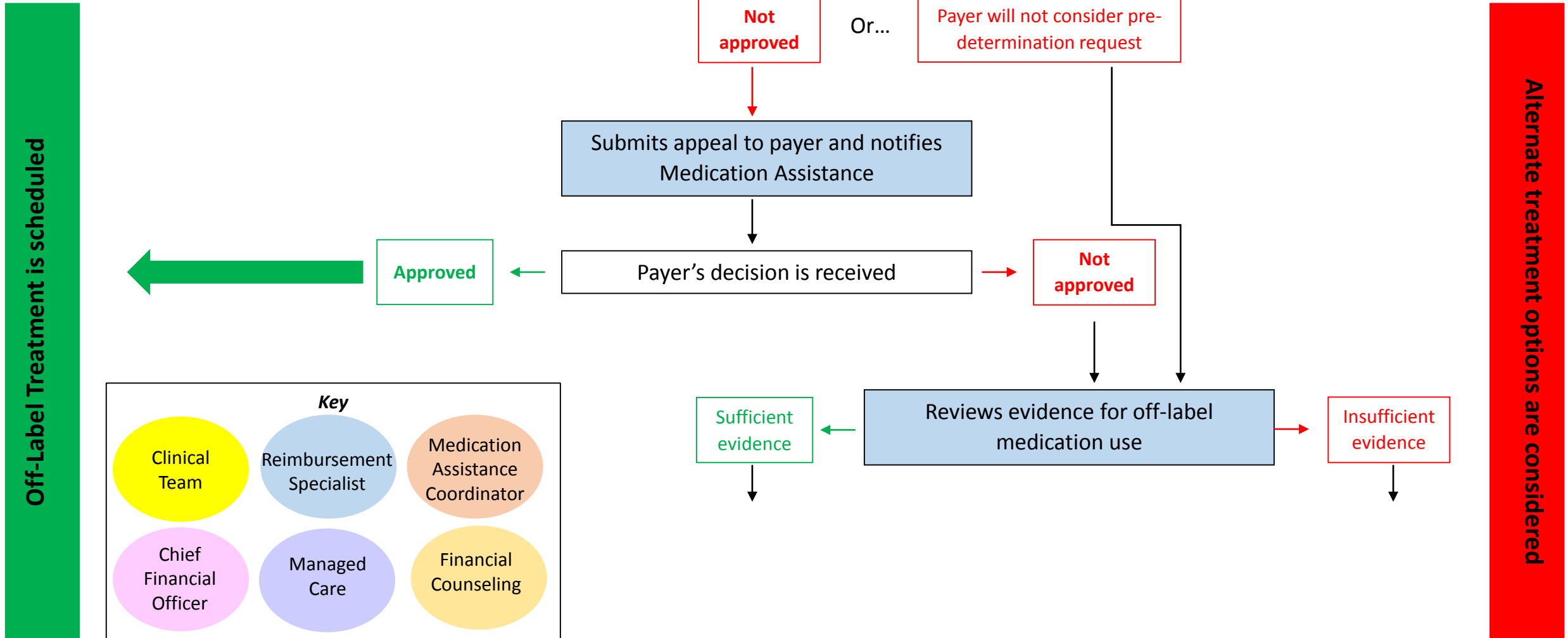
Alternate treatment options are considered



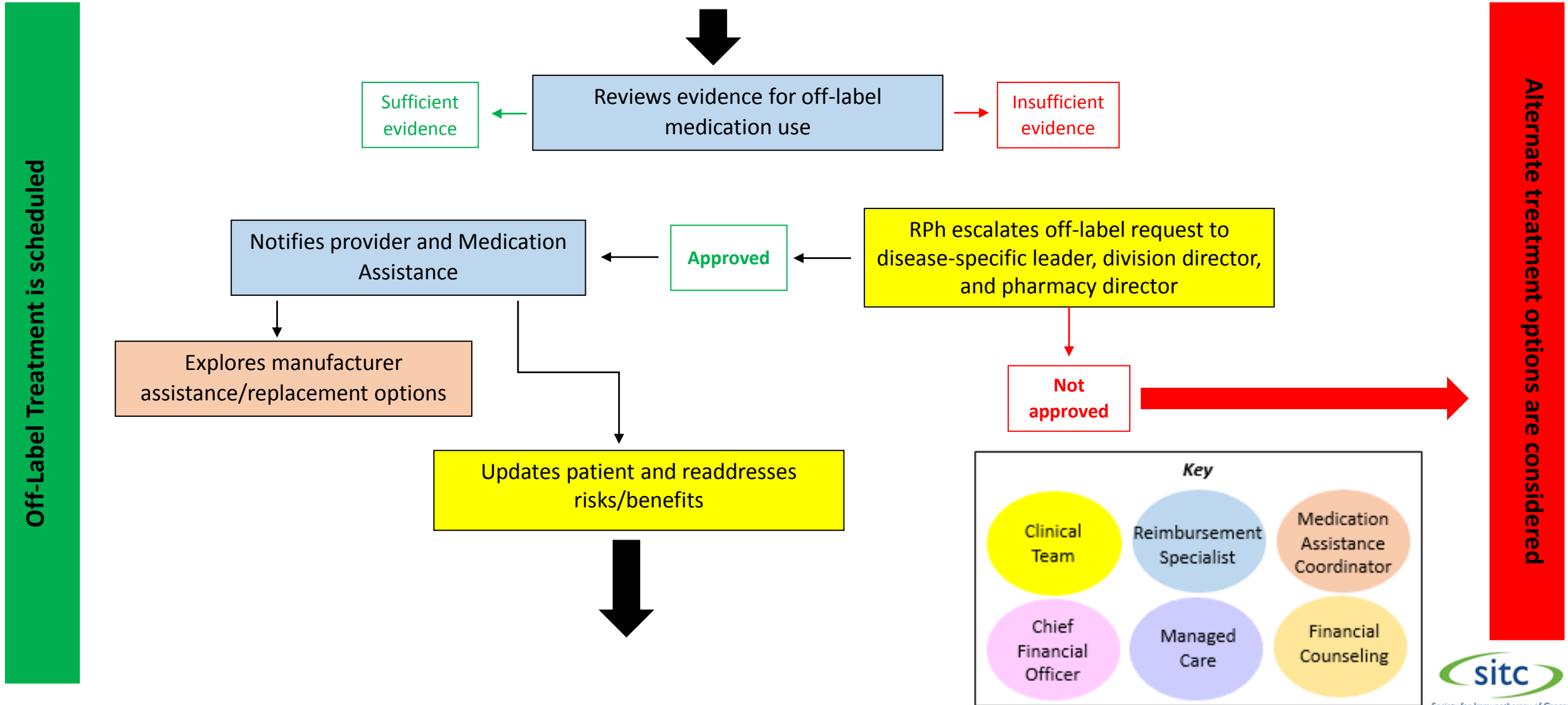
Off-Label Medication Process: *Commercial Payers*



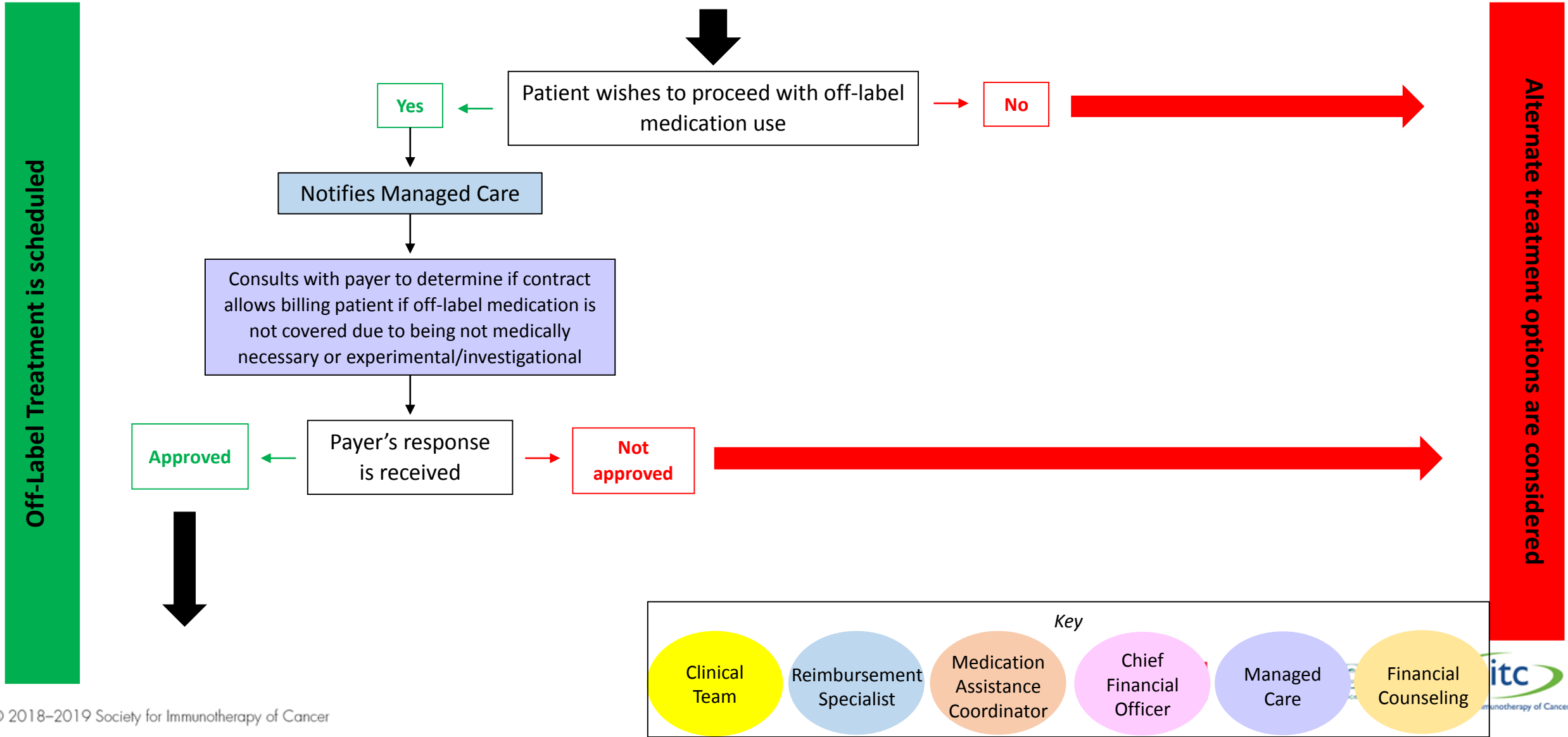
Off-Label Medication Process: Commercial Payers



Off-Label Medication Process: *Commercial Payers*

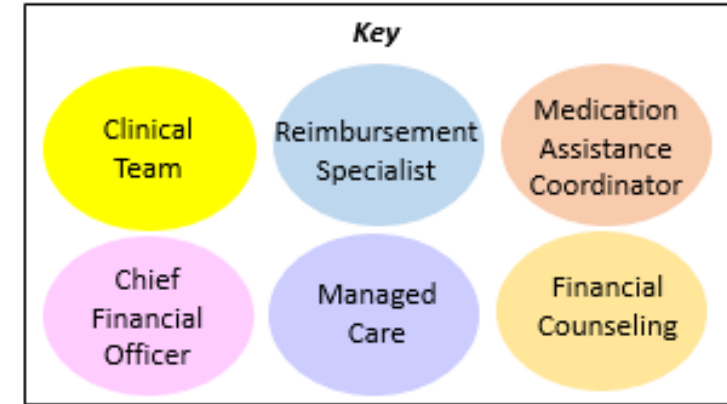
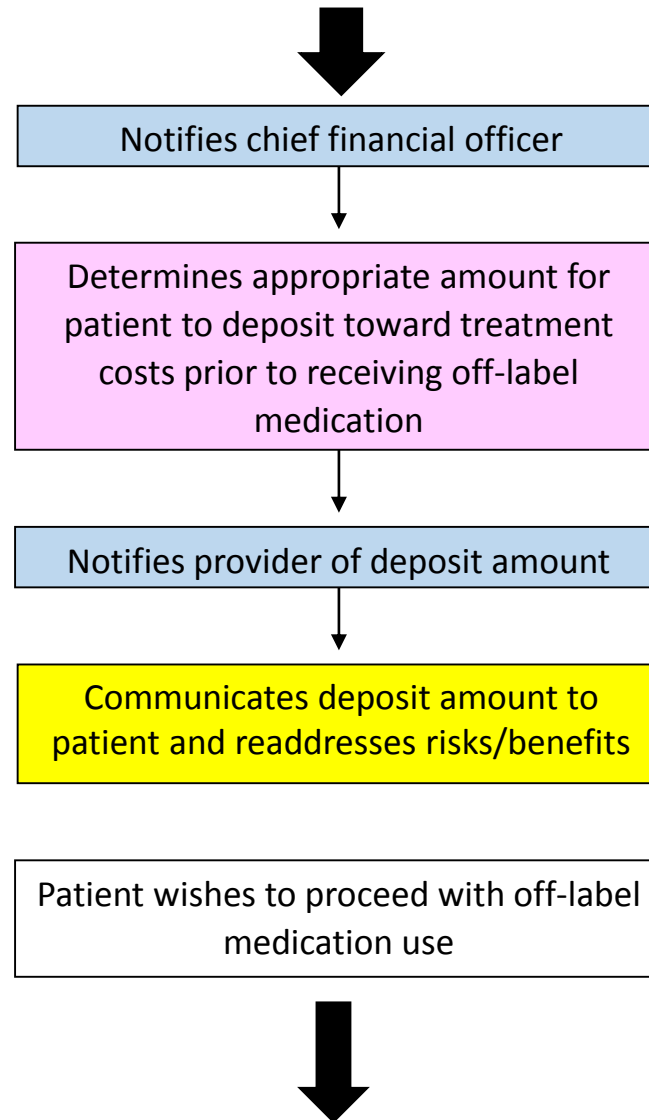


Off-Label Medication Process: *Commercial Payers*



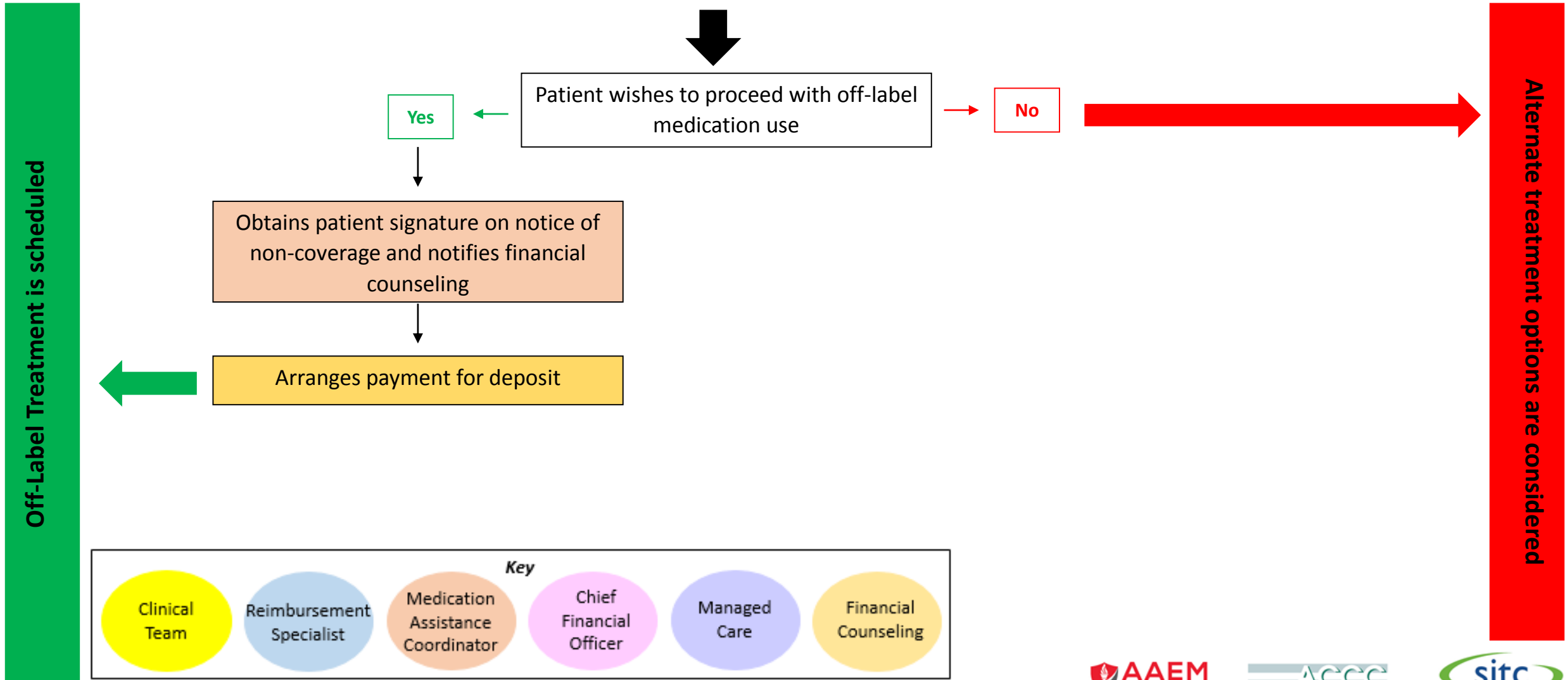
Off-Label Medication Process: *Commercial Payers*

Off-Label Treatment is scheduled



Alternate treatment options are considered

Off-Label Medication Process: *Commercial Payers*



Denials – Common Reasons

- Lack of pre-certification or authorization
- Medical necessity
- Experimental and investigational
- Requires additional information
- Non-covered service/medication on the plan benefit
- Out of network provider
- Timely filing of claims
- Multiple diagnoses coding 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

Case Example: 1

- Request for Ipilimumab 3mg/kg and Nivolumab 1mg/kg every 3 weeks combination followed by Nivolumab 3mg/kg every 2 weeks for metastatic melanoma to the genital region & lymph node
- Diagnosis code: C43.72, C79.82, C77.4
- Insurance: Anthem
- Cost of therapy: \$136,728
- Level of evidence:
 - NCCN level of evidence 2A
 - Anthem clinical policy

Case Example: 1

- Initial thoughts?
 - Case meets NCCN and Anthem Clinical policy guidelines
- Concern for reimbursement?
 - None
- What happened next...
 - Denied for Experimental and Investigational usage

Case Example: 1

- Final outcome
 - Submit an appeal that contained:
 - Infusion orders and pharmacy records
 - Nursing administration and performance status assessment
 - Prescriber clinical records
 - Authorization for treatment from AIM pharmacy specialty services (AIM Specialty Health)
 - Current lab and scan results
- Appeal successful and reimbursement granted

Case Example: 2

- Request for nivolumab 3mg/kg every 2 weeks for metastatic epithelioid sarcoma with metastatic disease to the lung, scalp, kidney and soft tissue
- Diagnosis code: C49.9, C78.02, C77.4
- Insurance: Aetna
- Cost of therapy: \$75,064
- Level of evidence: Case studies

Case Example: 2

- Initial thoughts?
 - Patient has failed multiple lines of therapy
 - Aggressive disease
 - Limited data
- Concern for reimbursement?
 - High concern for denial
- What happened next...
 - Complete pharmaceutical enrollment form
 - Submit pre-determination

Case Example: 2

- Final Outcome:
 - The pre-determination was submitted to Aetna
 - Initially the case was denied for experimental and investigational
 - Peer to peer appeal was arranged
 - Denial was over turned
 - Claims were resubmitted
 - Appeal successful and reimbursement granted

Case Example: 3

- Request for nivolumab 3mg/kg every 2 weeks for NSCLC in July, 2016
- Diagnosis code: 162.9 (ICD 9)
- Insurance: Aetna
- Cost of therapy: \$75,064
- FDA approved package insert
- Patient weight: 110kg

Case Example: 3

- Initial thoughts?
 - Within indication at time of initiation
- Concern for reimbursement?
 - FDA updated dosing in September 2016
 - 240mg flat dose
- What happened next...
 - October claims denied due to excessive billing units

Case Example: 3

- Final Outcome:
 - The pre-determination was submitted to Aetna
 - Case was approved with current FDA approved dose
 - Reimbursement was denied based on dose
 - Peer to peer appeal was arranged
 - Denial was over turned
 - Claims were resubmitted
 - Appeal successful and reimbursement granted

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