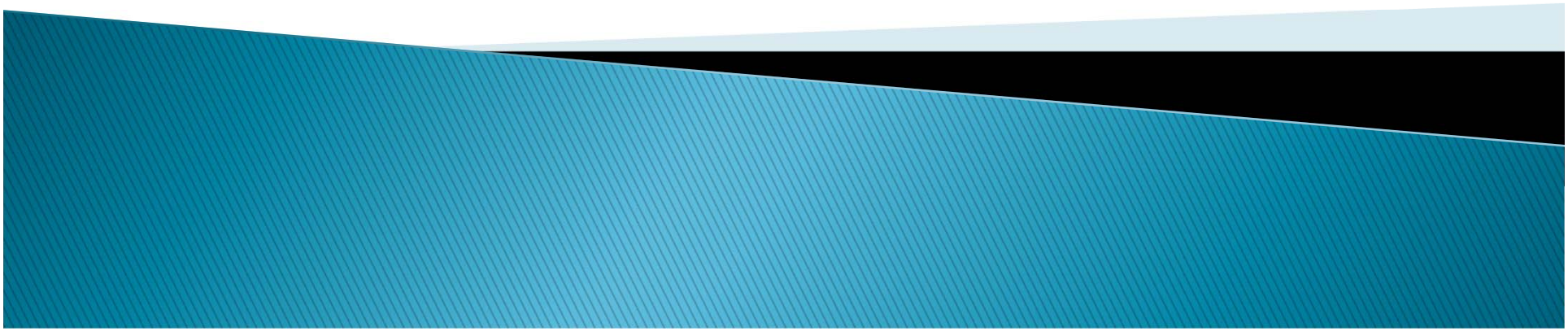
Cost Containment Challenges and Strategies for Oncology Providers

Niesha Griffith, MS, RPh, FASHP

ACE Annual Conference 2018
Portland, Oregon



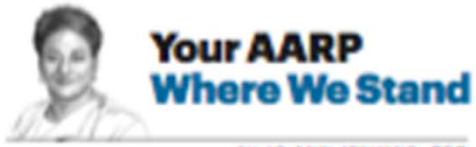
Objectives

- Describe challenges related to containing medication and related costs in the current healthcare environment
- Outline strategies for cost containment
- Discuss strategies for enhancing revenue

Financial Toxicity, Part I: A New Name for a Growing Problem

Financial Toxicity and Societal Costs of Cancer Care: Distinct Problems Require Distinct Solutions

'Financial Toxicity': Still a Pressing Concern for Patients With Cancer



Let's Cut Drug Costs

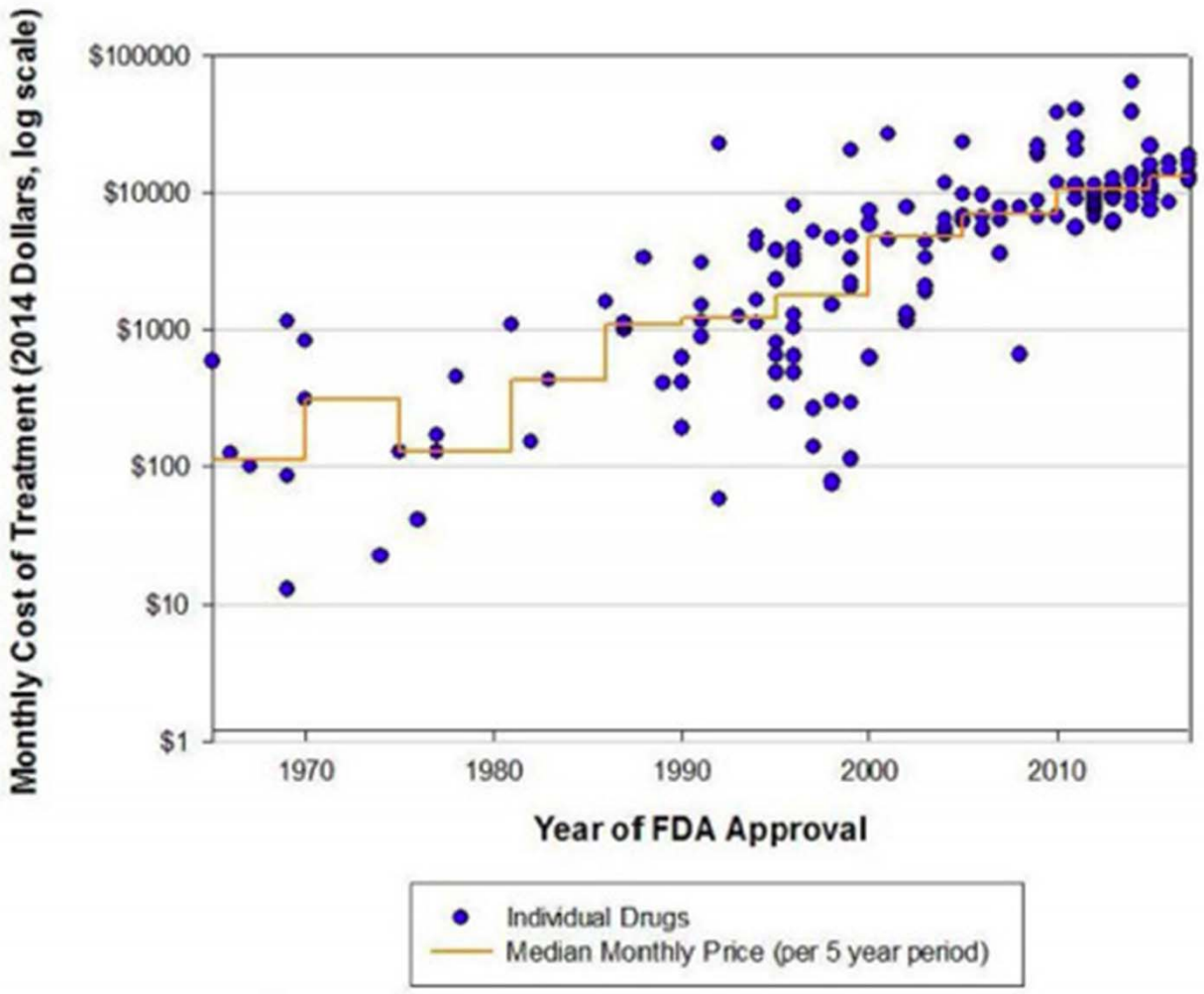
Prices doubled in 10 years. That's too much

Insured Cancer Patients Face Financial Toxicity, Study Finds

The Financial Toxicity of Cancer Treatment: A Pilot Study Assessing Out-of-Pocket Expenses and the Insured Cancer Patient's Experience

Financial Toxicity of Cancer Care: It's Time to Intervene

Monthly and Median Costs of Cancer Drugs at the Time of FDA Approval 1965-2017



Source: Peter B. Bach, MD, Memorial Sloan Kettering Cancer Center

THE WALL STREET JOURNAL.

Cancer Drug Wins Support From Panel

Updated Nov. 18, 2010 12:01 a.m. ET

A new treatment for prostate cancer called Provenge won a vote of confidence from a Medicare coverage advisory committee Wednesday suggesting the federal program is likely to pay for the $93,000-per-patient medicine.

The committee, made up of health industry experts, doctors and researchers, found enough evidence to support the use of the medicine for late-stage prostate-cancer patients whose disease has metastasized, but not for those whose cancer hasn't progressed. A final decision from Medicare is expected in several months. The agency isn't required to follow the committee's advice.

By JIM EDWARDS / MONEYWATCH / March 28, 2011, 12:32 PM

MONEYWATCH

Some Inconvenient Facts About Yervoy, Bristol-Myers' New "Holy Grail" Cancer Drug

After **Bristol-Myers Squibb** (BMY)'s new "Holy Grail" cancer drug **Yervoy** was approved by the FDA on Friday, CEO **Lamberto Andreotti** told the Wall Street Journal, "R&D pays ... It pays not only because we have results, but because we invest our money very carefully." The remark was a jab at companies like **Pfizer** (PFE), which recently reduced its commitment to R&D spending in the belief that massive corporate outlays are inefficient compared to smaller, nimbler operations.

But Yervoy -- a fascinating new drug that boosts the body's own immune system to attack cancer cells -- wasn't developed at BMS, as Andreotti implied. It was developed by a small company named **Medarex** that BMS acquired for $2.1 billion in 2009, which would suggest the opposite -- that large corporations' R&D budgets are less significant than their M&A budgets.

That's not the only inconvenient fact about Yervoy (also known as ipilimumab). The drug -- once hailed by its researchers as the "Holy Grail" of cancer -- costs $120,000 for a four-dose course of injections, and taxpayers will pick up a large chunk of the cost of that. That's because Yervoy is an injectable drug, and thus falls into the nonsensical legal loophole that requires federal programs such as Medicare and Medicaid to pay the full cost of the drug, without negotiating its price, simply because it's a series of injections rather than pills.

Opinion | OP-ED CONTRIBUTOR

The New York Times

In Cancer Care, Cost Matters

By PETER B. BACH, LEONARD B. SALTZ and ROBERT E. WITTES OCT. 14, 2012

AT Memorial Sloan-Kettering Cancer Center, we recently made a decision that should have been a no-brainer: we are not going to give a phenomenally expensive new cancer drug to our patients.

The reasons are simple: The drug, Zaltrap, has proved to be no better than a similar medicine we already have for advanced colorectal cancer, while its price — at $11,063 on average for a month of treatment — is more than twice as high.

BUSINESS DAY

Sanofi Halves Price of Cancer Drug Zaltrap After Sloan-Kettering Rejection

By ANDREW POLLACK NOV. 8, 2012

In an unusual move, a big drug company said on Thursday that it would effectively cut in half the price of a new cancer drug after a leading cancer center said it would not use the drug because it was too expensive.

WHY DRUGS COST SO MUCH

Nothing stops drug companies from charging the highest price the market will bear. The result: prices that make little sense, but lots of profit

Prescription drug prices in America are among the highest in the world. On the campaign trail, President Trump said drug companies were "getting away with murder." Is that true? Or are these firms the beneficiaries of a system that turns a blind eye to excessive profit-making at the expense of society? In this report, we explain in simple, clear terms why drugs cost what they do. We also examine the drug-price debate in Washington, explain how the complicated business of medicine works and give you ways to save money at the pharmacy. AARP stands by your side to help lower drug costs and make sure all Americans over 50 have affordable access to the medicine they need to live their fullest lives.

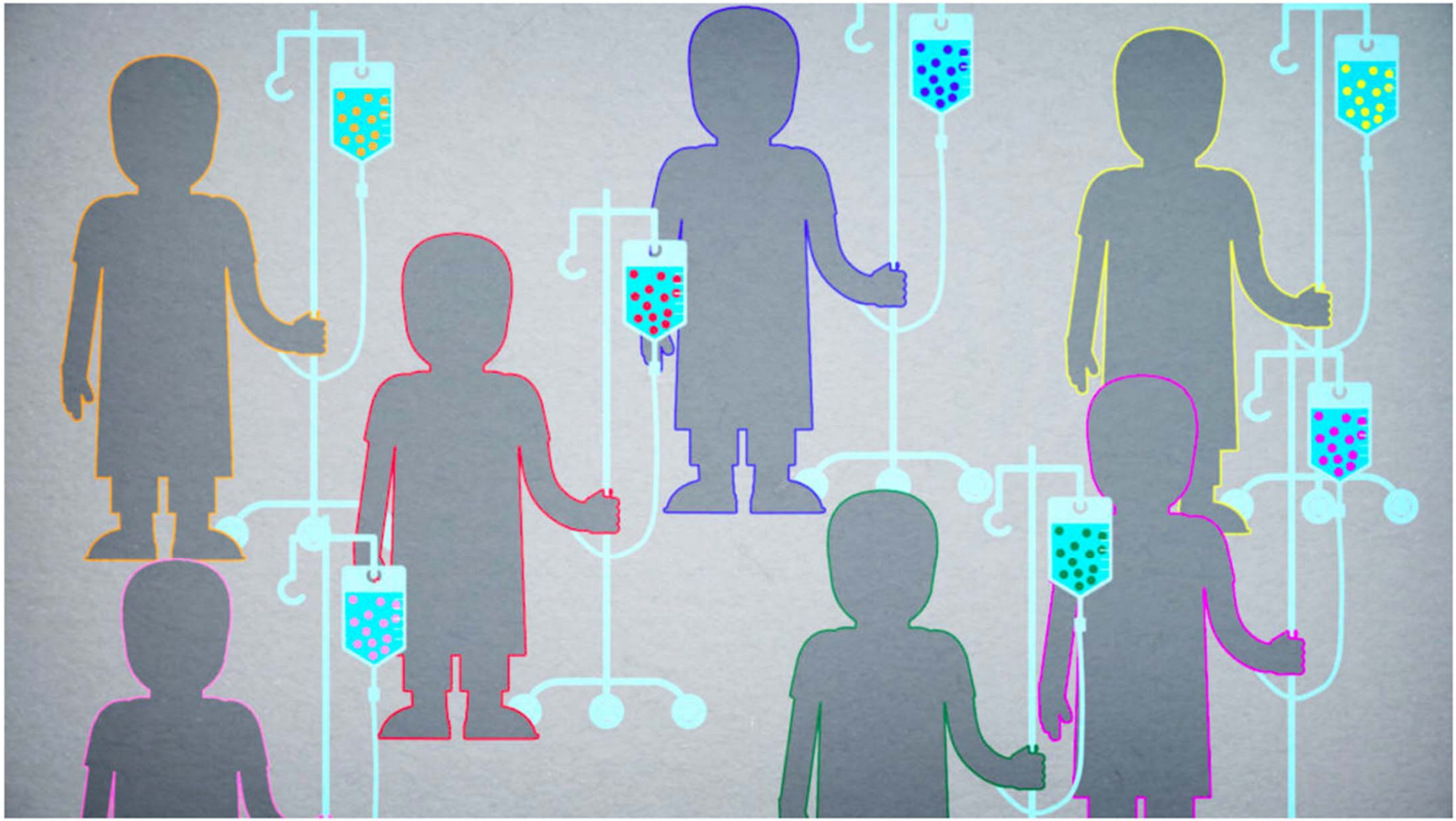
—Robert Love, editor in chief

STAT

FIRST OPINION

A $475,000 price tag for a new cancer drug: crazy or meh?

By ANNA KALTENBOECK *and* PETER B. BACH / AUGUST 31, 2017



Cost Containment Challenges

- Medication Costs
  - New novel agents/new indications
  - Frequent price increases
  - Companion diagnostics/biomarker testing
- Medications shortages
- IV medication waste
- Unfunded regulatory mandates
- Off-label medication use
- Inventory and contract management
- Restricted distribution

Medication Costs

Generic Name FDA Approval	Brand Name Manufacturer	Indication	Cost
Eculizumab 2007	Soliris® Alexion	Hemolytic uremic syndrome (atypical) and paroxysmal nocturnal hemoglobinuria	$450,000 (annual) 2010 – Most expensive drug in the world
Sipuleucel-T 2010	Provenge® Dendreon	Hormone refractory prostate cancer; metastatic	$93,000 (3 infusions)
Ipilimumab 2011	Yervoy® BMS	Malignant melanoma	$96,000 (4 doses)
Brentuximab 2011	Adcetris®	Anaplastic large T-Cell systemic malignant lymphoma, Hodgkin's Disease	$216,000 (16 doses)
Pertuzumab 2012	Perjeta® Genetech	Breast cancer	$89,900 (17 cycles)

Medication Costs

Generic Name FDA approval	Brand Name Manufacturer	Indication	Cost
Glucarpidase 2012	Voraxaze® BTG international	Methotrexate toxicity	$112,500 (one treatment)
Pembrolizumab 2014	Keytruda® Merck	Malignant melanoma	$150,000 (annual)
Blinatumomab 2014	Blincyto® Amgen	Relapsed/refractory ALL	$178,000 (annual)
Nivolumab 2014	Opdivo® BMS	Metastatic Squamous NSCLC	$150,000 (annual)
Talimogene laherparepvec 2015	Imlygic® Amgen	Recurrent melanoma lesions	$65,000 (annual)
Daratumumab 2015	Darzalex® Janssen	Multiple myeloma	$135,000 (annual)
Uridine triacetate 2015	Vistogard® Wellstat	Fluorouracil or capecitabine overdose	$75,000 (one dose)

Medication Costs

Generic Name FDA approval	Brand Name Manufacturer	Indication	Cost
Elotuzumab 2015	Empliciti® BMS	Multiple myeloma	$142,000 (annual)
Difibrotide 2016	Defitelio® Jazz	Hepatic veno-occlusive disease following HSCT	$156,000 (annual)
Atezolizumab 2016	Tecentriq® Genentech	Locally advanced or metastic urothelial carcinoma	$150,000 (annual)
Olaratumab 2016	Lartruvo® Lilly	Soft tissue sarcoma	$200,000 (annual)
Tisagenlecleucel 2017	Kymriah® Novartis	Relapsed/refractory B-cell precursor ALL (up to age 25yr)	$475,000 (one course)
Axicabtagene ciloleucel 2017	Yescarta® Kite	Relapsed/refractory large B-cell lymphoma (adults)	$373,00 (one course)

Cost Containment Challenges

- Medication shortages
  - "Hoarding" (increased with 6 month notice requirement)
  - Gray market price "gouging"
  - Use of more expensive alternative
    - Generic paclitaxel vs. docetaxel or Abraxane®
    - Mitomycin C cost increased with BCG shortage
- IV Medication Waste
  - Most newer agents provided as SDVs* only
  - Available vial sizes lead to excessive waste
- Unfunded regulatory mandates
  - USP 797/800 requirements
  - REMS program requirements

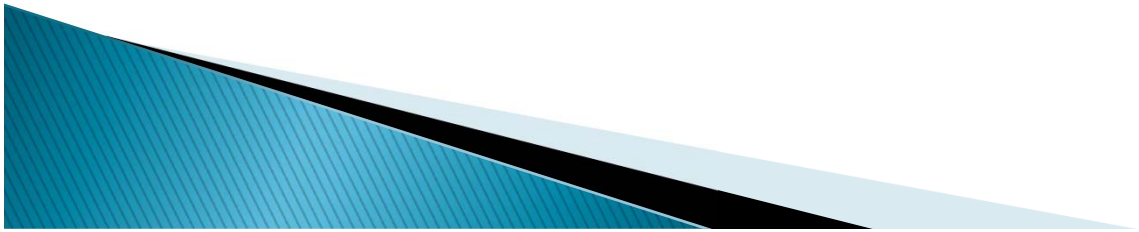
*single dose vials

Cost Containment Challenges

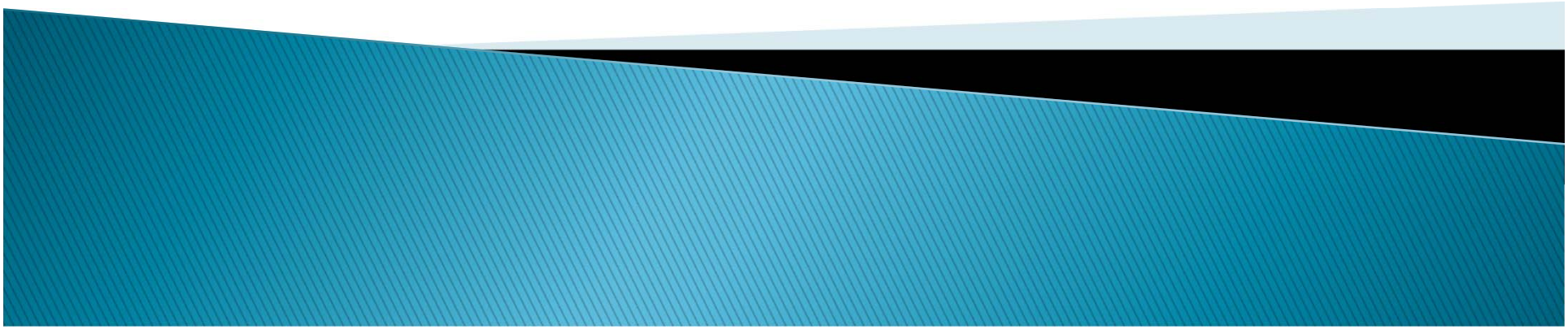
- Off-label medication use
  - Frequency of requests
    - Combinations, doses, lines of therapy
  - Resource intense requirements
  - Differing payer rules
    - Government/Commercial
  - Various compendia
    - American Hospital Formulary Service Drug Information®
    - Elesevier Gold Standard *Clinical Pharmacology*®
    - Truven Health Analytics Micromedex Drugdex®
    - National Comprehensive Cancer Network Drugs and Biologics Compendium®
    - Wolters Kluwer Lexi-Drugs®

Cost Containment Challenges

- Inventory and contract management
  - Multiple sites and inventories
  - Class of trade, market share, rebates, and pricing
- Restricted distribution
  - Loss of volume credit
  - Loss of wholesaler discount
  - Credit checks
  - Purchase orders
    - Multiple levels of approval
  - Multiple accounts
- Personnel resources to manage all of the above and more



Cost Containment Strategies



Cost Containment Strategies

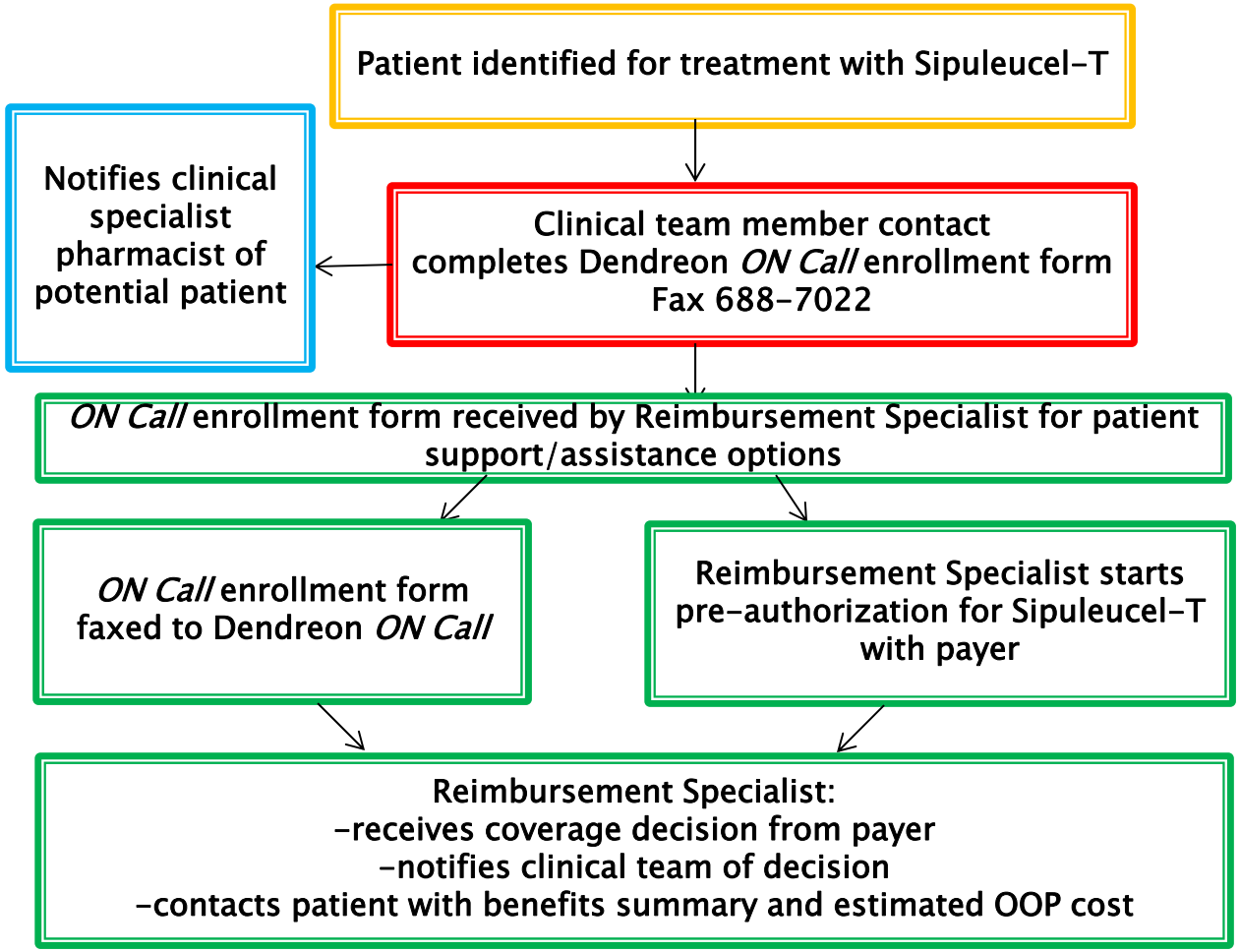
Medication Costs

- Develop high dollar chemotherapy process
  - Include medications where annual cost for treatment is > $50,000
  - Require precertification regardless of payer policy, especially for new agents
    - Ensures insurance reimbursement
    - Identifies patients in need of medication assistance
    - Informs patients of their financial obligation before treatment
  - Enroll patient in manufacturer assistance program
  - Consider use of algorithms to ensure clarity of roles and responsibility

Provenge® Workflow

Legend:

Orange–Physician
Blue–Pharmacy
Red–Clinical Team
Green–Reimbursement
Purple–MAP



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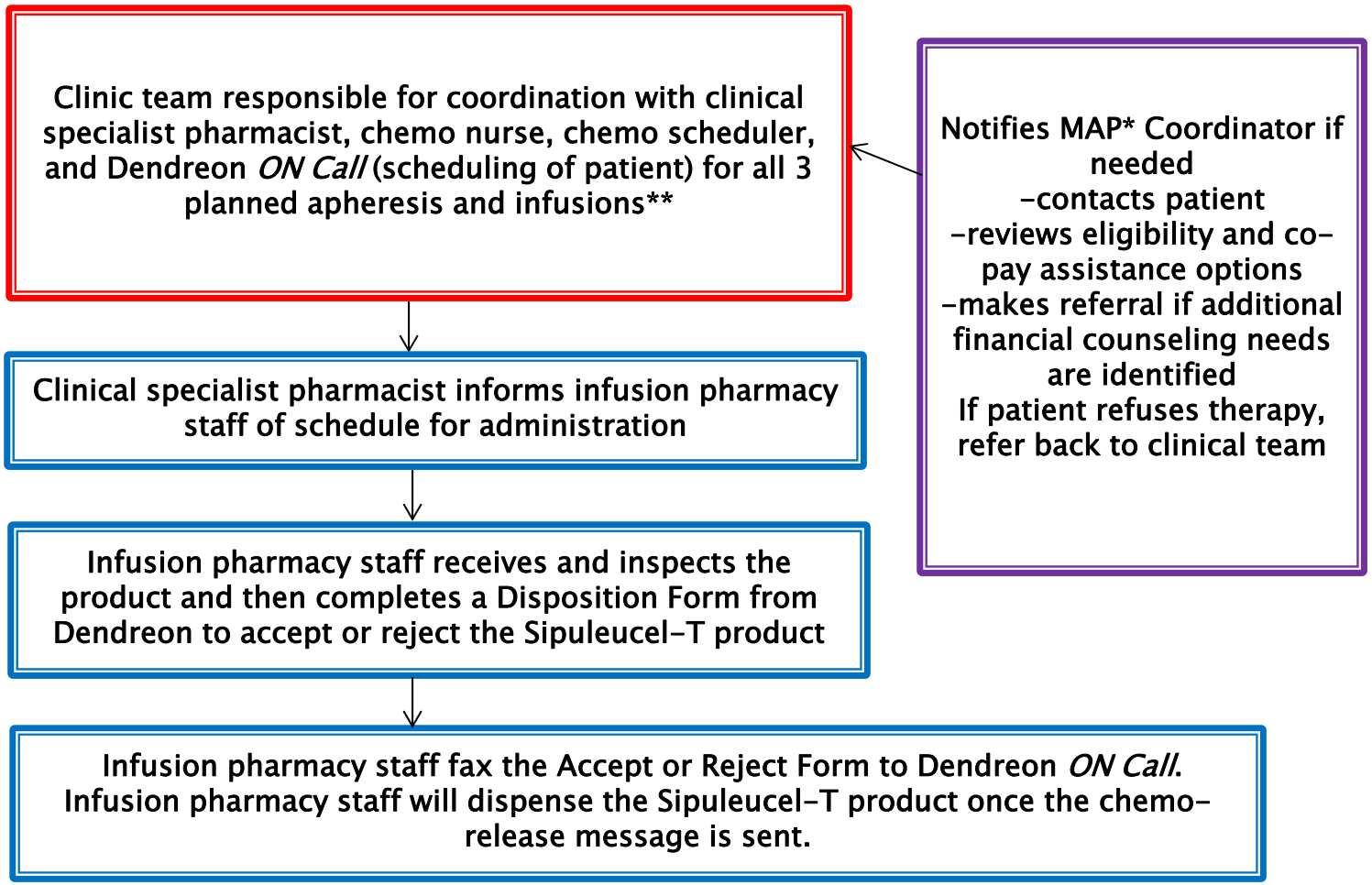


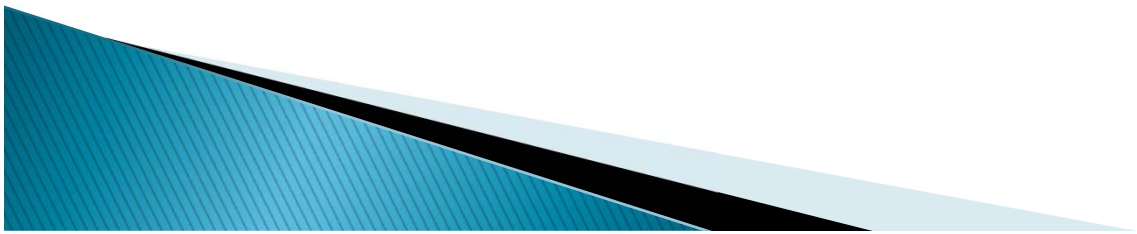
*MAP- Medication Assistance Program

** Patients will only be scheduled to receive Sipuleucel-T at Kenny Road site only. Patients must be scheduled for apheresis at the Dendreon specified site on Monday, Tuesday, or Friday. Patients must receive the Sipuleucel-T infusion on Day 3 or Day 4 following apheresis .

Cost Containment Strategies

Medication Costs

- Develop high dollar chemotherapy process (cont.)
  - Create database for tracking status of all claims (approval, payment, denial, appeal)
    - Make available to Pharmacy and Finance staff to improve communication
    - Report reimbursement status to P&T Committee
- Monitor unreconciled medications dispense reports for high cost medications (if charge on administration)
- Utilize 340B (where possible)



Cost Containment Strategies

Medication Costs

- Standardize ordering
  - Comprehensive treatment plans
    - Pre-medications, supportive care medications
- Develop/utilize treatment algorithm/pathways
- Consider use of biosimilars and ability to negotiate with manufacturer of reference product
  - Traztuzumab and bevacizumab approved but not available
- Establish preferred agents/therapeutic interchange
  - Leuprolide (Eligard®) vs. Goserelin (Zoladex®)
  - Panitumumab (Vectibix®) vs. Cetuximab (Erbitux®)

Cost Containment Strategies

Medication Costs

- Add medications to formulary with restrictions
  - Restrict to FDA approved indications
  - Restrict to outpatient setting
    - Supportive care – pegfilgrastim (Neulasta®), octreotide LAR (Sandostatin LAR®), denosumab (Xgeva®), luteinizing hormone-releasing hormone agonist (including female HSCT transplant patients prior to admission)
    - Cancer treatment – atezolizumab (Tecentriq®), daratumumab (Darzalex®),elotuzumab (Empliciti®), ipilimumab (Yervoy®), nivolumab (Opdivo®), ofatumumab (Arzerra®), pembrolizumab (Keytruda®), pertuzumab (Perjeta®), talimogene (Imlygic®), trastuzumab (Herceptin®)
    - **Inpatient chemotherapy use policy critical to success**

Cost Containment Strategies

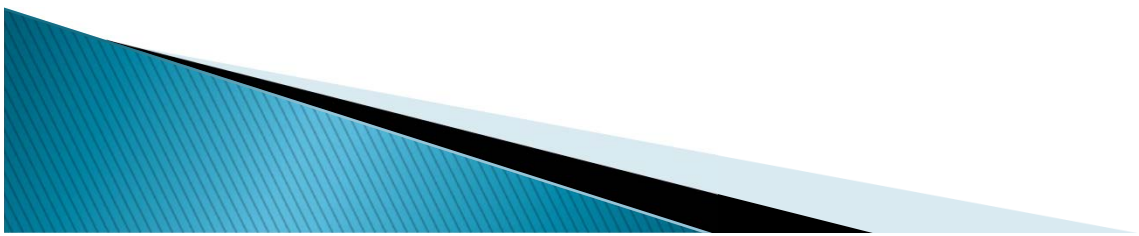
Medications Costs

- Modify inpatient dosage of medications
  - Darbepoetin (Aranesp®)
- Keep current with medication specific programs
  - Imlygic® Cost Cap Program
- Develop requirements for clinical trials
  - Provision of/payment for off label uses of SOC medications
  - Supportive care agent use must support institutional guidelines – e.g.Rasburicase (Elitek®)
- Bulk purchase when price increases anticipated
- Request institution specific contracting (independent of GPO)

Cost Containment Strategies

Medication Costs

- Utilize pharmaceutical manufacturer medication assistance programs for uninsured/underinsured
  - Inpatient/outpatient replacement, take home medications
  - Dedicate staff to collect patient financial/clinical information and signatures, obtain provider signatures, complete applications
  - Involve providers to ensure compliance when receiving, handling, and dispensing medications



Cost Containment Strategies

Medication Costs

- Utilize pharmaceutical manufacturer medication copay assistance programs
  - Oral chemotherapy, transplant, HIV medications
  - Limited number of IV medications

    Note: Some of these IV assistance programs are NOT user friendly for large organizations
- Utilize copay foundations (i.e., disease-based assistance) for IV and oral high cost medications
  - Healthwell, Patient Access Network Foundations, Cancer Care, Leukemia, and Lymphoma Society, etc.

Cost Containment Strategies

IV Medication Waste

- Stock multiple vial sizes for medications that come as SDVs
- Leave SDVs in hood for up to 6 hours*
  - Use CSTD** to extend dating of SDVs up to 7 days*** (i.e., drug vial optimization)
- Coordinate/standardize administration times (aka "block scheduling")
  - Aldesleukin (Proleukin®)
  - Melphalan (Alkeran®)
- Round to the nearest vial size
  - Create rounding tables
  - Customize EMR

*USP <797> Pharmaceutical Compounding Sterile Preparations. 2007
**Closed System Transfer Device
***McMichael et al. Am J Pharm Benefits. 2011; 3(1):31-8.

Memorial Sloan Kettering Cancer Center Chemotherapy Dose Rounding Rules

Dose Range		Rounds to nearest	Examples of maximum rounding
n/a	≤0.01	exact dose	n/a
>0.01	0.05	0.001	0.0105 becomes 0.011
>0.05	0.1	0.005	0.0525 becomes 0.055
>0.1	0.5	0.01	0.105 becomes 0.11
>0.5	1	0.05	0.525 becomes 0.55
>1	5	0.1	1.05 becomes 1.1
>5	10	0.5	5.25 becomes 5.5
>10	50	1	10.5 becomes 11
>50	100	5	52.5 becomes 55
>100	500	10	105 becomes 110
>500	1,000	50	525 becomes 550
>1000	5,000	100	1,050 becomes 1,100
>5000	10,000	500	5,250 becomes 5,500
>10,000	n/a	500	10,250 becomes 10,500

Provided courtesy of Ray Muller, MS, RPh
Associate Director of Pharmacy

Caution- Dose rounding may lead to insurance denials! This is payer dependent; they may use as a reason to deny the entire billed dose (even if lower). Important to address proactively with payers if issues arise.

Cost Containment Strategies

Regulatory requirements

- Decrease waste associated with USP 797 requirements by utilizing CSTD* for drug vial optimization
- Ensure consultants/engineers are well versed on USP 797/800 to avoid costly mistakes
- Develop policy and procedures to streamline implementation of REMS programs
  - Integrate into current practice to the extent possible
  - Cleary define roles of staff
  - Utilize EMR and decision support to ensure compliance

*Device received FDA approval to extend product stability up to 7 days (September 2012) http://www.accessdata.fda.gov/cdrh_docs/pdf12/K120384.pdf (Accessed April 29, 2013)

Cost Containment Strategies

Medication Shortages

- Take a pro-active approach to daily monitoring
  - Wholesaler information
  - Websites (ASHP, FDA)
- Dedicate staff
  - Coordination of supplies between sites
  - Centralizing ordering of medications on allocation
  - Daily monitoring of supply on hand
  - Coordination of stakeholder meetings
  - Daily/weekly communications to key stakeholders regarding supply on hand
  - Managing the “bread, butter, and milk” list

Cost Containment Strategies

Off-Label Medication Use

- Require clinical evidence/compendia support for off-label indications
- Develop policy and process
  - Require supportive evidence
    - Two Phase 2 studies or one Phase 3 study from peer-reviewed medical journal*
    - Local coverage or national coverage determination support (LCD, NCD)
    - Compendia support
  - Incorporate peer review and escalation of requests

*www.cms.hhs.gov

Cost Containment Strategies

Off-Label Medication Use

- Designate/dedicate staff* for predetermination
- Gather information (patient specific, supporting evidence)
  - Draft letters of medical necessity
  - Contact payer for approval
  - Coordinate patient signature requirements with financial counseling (ABN, NONC**)
  - Track information (approval/disapprovals, payments/denials)
  - Coordinate peer to peer discussions
  - Coordinate and submit appeals
  - Work closely with team (physician, nurse practitioner, pharmacist) throughout process

*Individual with clinical experience; knowledge of medical terminology, chemotherapy regimens, payer rules, etc. (nurse preferred)

**ABN – Advanced Beneficiary Notice, NONC – Notice of Non Coverage

Cost Containment Strategies

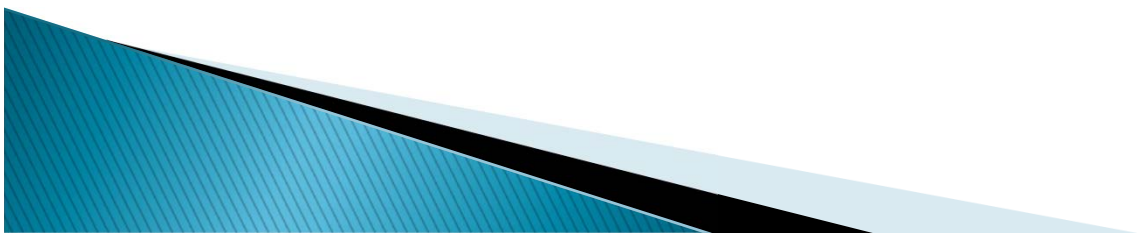
Off-Label Medication Use

- Educate physicians
  - Policy and approval process
  - Timeline for approval (e.g., ten business days)
  - Specific role in requests for approval/appeals
  - Patient discussion requirements
    - Risks/benefits of therapy
    - Requirement to sign ABN or NONC
- Educate other providers (advanced practice providers, pharmacists, nurses, etc.)
  - Accessing compendia, LCDs, NCDs
  - Policy re-enforcement

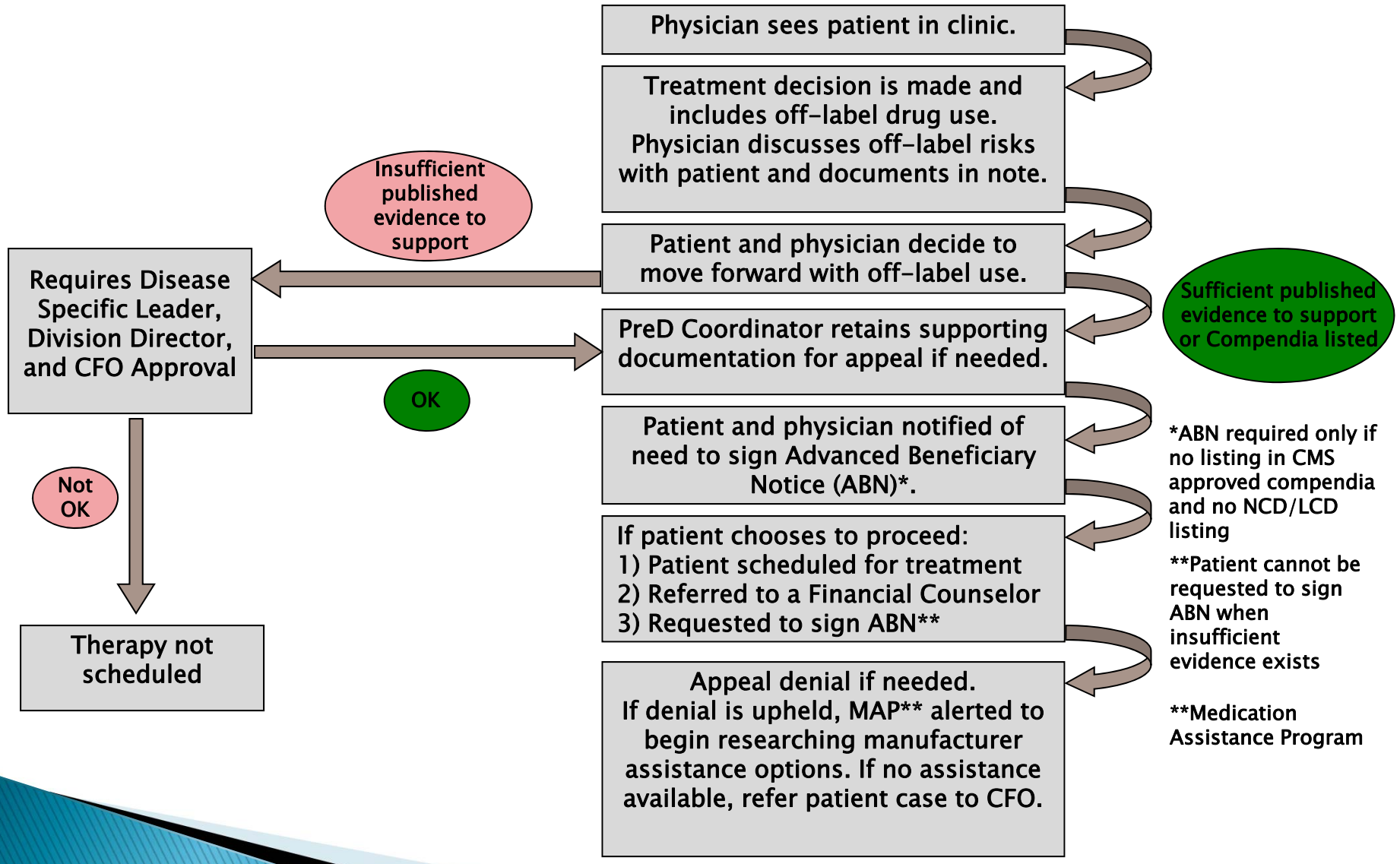
Cost Containment Strategies

Off-Label Medication Use

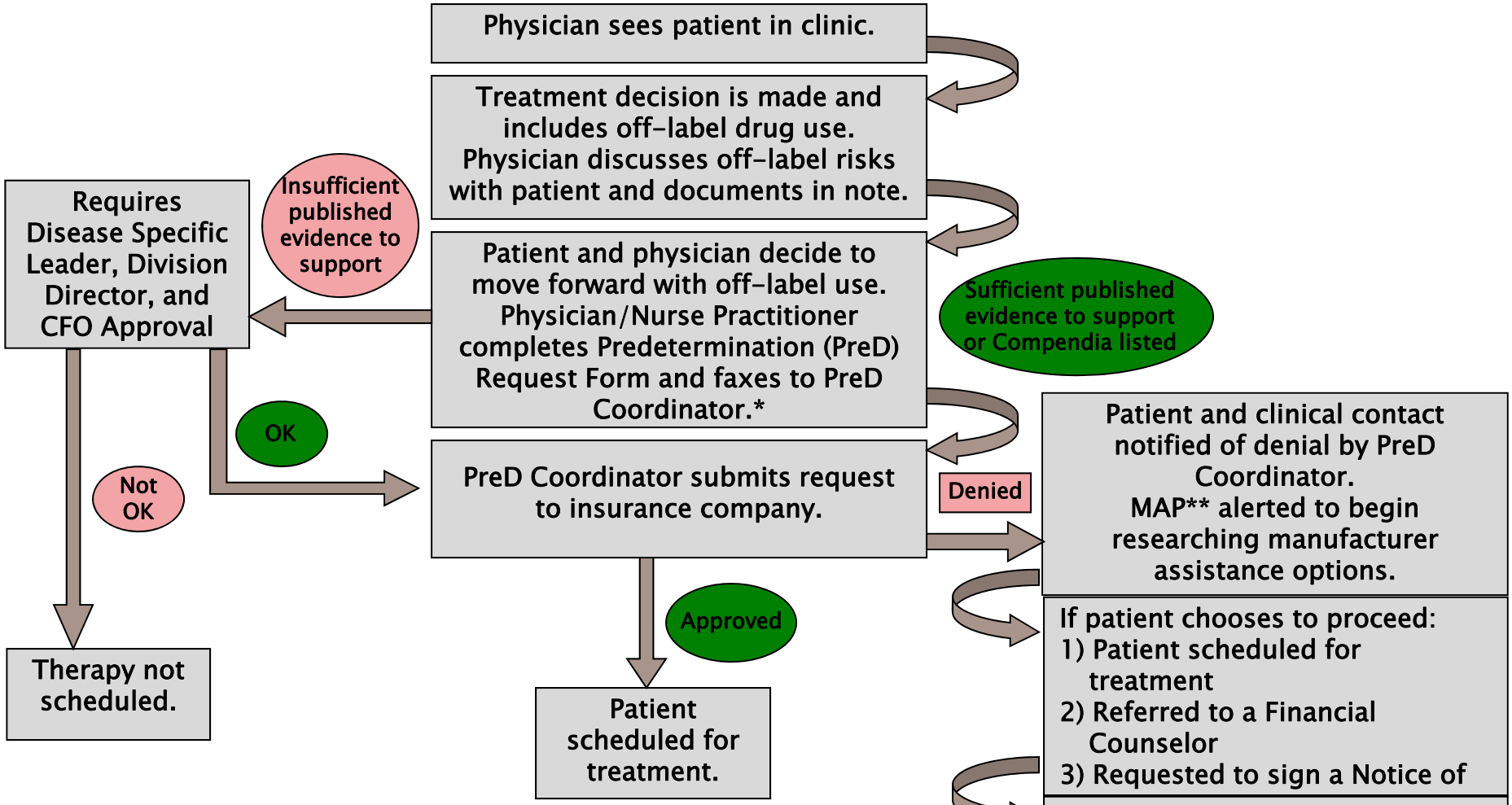
- Utilize pharmaceutical manufacturer assistance programs
  - Claims assistance
    - Perform benefits investigation
    - Assist with prior authorization
  - Appeals assistance
    - Follow claims before and after denials
    - Provide supporting clinical evidence
    - Arrange peer to peer discussion
  - Replacement programs based on diagnosis



Medicare Process



Commercial Payer Process



*10 business days minimum notice required to process PreD

**Medication Assistance Program

Cost Containment Strategies

Inventory and Contract Management

- Implement inventory control systems
  - Manual – Kanban
  - Electronic – wholesaler solutions such as Min/Max
- Reconcile dispenses to purchases monthly (esp. top 80/20 items) to ensure inventory turnover and no diversion
- Monitor reverse distributor reports (returns) for areas of improvement and accuracy
- Centralize location of low use/high cost agents to enable sharing between sites
  - Dexrazoxane for extravasations

Cost Containment Strategies

Inventory and Contract Management

- Contract Management
  - Be mindful of rebate/market share requirements and timelines
  - Ensure manufacturer recognizes you in the correct class of trade (e.g. hospital based, physician office)
    - The group purchasing organization (GPO) is the one that sets up the class of trade
    - Many companies have their own paperwork that must be completed in addition to GPO
  - Check regularly to make sure that contracts/prices are correct
    - Wholesaler may have reports to assist with this but you must be proactive

Cost Containment Strategies

Restricted Distribution

- Actively discourage practice when meeting with pharmaceutical representatives
  - Increases cost to organization
  - Increases cost to patient
  - NOT a solution for a REMS requirement
- Seek hospital leadership and Pharmacy and Therapeutics Committee support to refuse addition to formulary until available through primary wholesaler
- Gain support through professional and group purchasing organizations

Cost Containment Strategies

Personnel Resources

- Adding resources may be unavoidable in larger institutions to effectively manage
  - Medication shortages
  - Off-label medication use
  - Pharmaceutical manufacturer assistance programs
  - Inventory and contracts
- Resources are also necessary to maximize utilization of EMR for decision support, policies and procedure enforcement, order standardization
  - Support appropriate ordering of high cost medications, curbing off-label medication use, managing REMS program requirements

Cost Containment Strategies

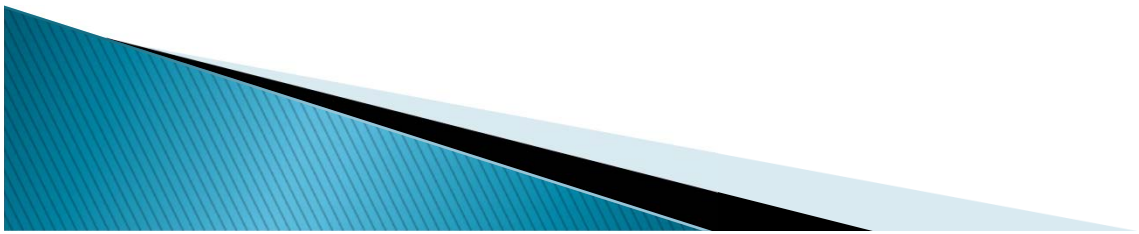
Personnel Resources

- Effectively utilize support and other clinical personnel, only involve providers where necessary
  - Purchasing manager or pharmacy technician to manage drug shortages and communicate with pharmacists
    - Pharmacists to communicate with providers
  - Nurse to pursue off-label approval
    - Pharmacist to assist with gathering of supportive evidence and policy compliance
  - Social worker, financial counselor, or pharmacy technician to access manufacturer assistance programs
    - Pharmacist/physician oversight of medications

Cost Containment Strategies

Personnel Resources

- Invest in robust financial infrastructure
  - Require double check of billing system updates to ensure billing units and multipliers are correct
  - Hire a dedicate medication reimbursement specialist
    - Work closely with payers and “ask for permission” in advance
      - Reconsideration packets
      - Updates to payer policies



Cost Containment Strategies

Personnel Resources

- Hire a dedicated medication reimbursement specialist (cont.)
  - Work closely with Finance Department and hospital Medicare specialist
  - Stay on top of changes in government and commercial payer policies
  - Involve clinical staff in review of denials
  - Chair a multi-disciplinary reimbursement committee
    - Reviews all high cost denials prior to write off
    - Monitors actual vs. expected reimbursement for high cost medications

Revenue Enhancement Opportunities

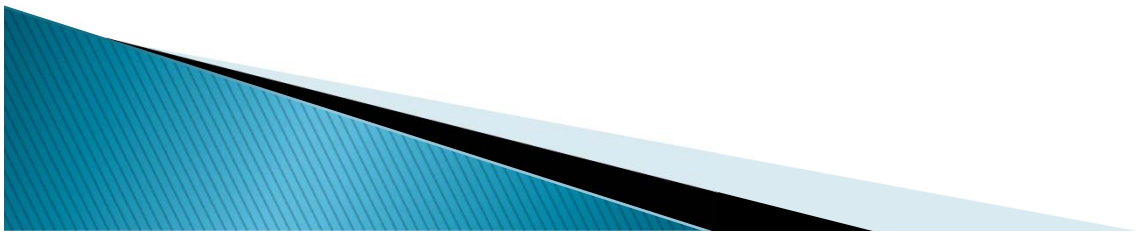
- Negotiate outlier payments
- Utilize New Technology Add-On Payment (NTAP) codes:
  - Bezlotoxumab (Zinplava)
  - Ustekinumab (Stelara)
  - Defibrotide (Defitelio)
  - Idarucizumab (Praxbind)
  - Uridine triacetate (Vistogard)

Blinatumomab (Blincyto) discontinued

*New technology add-on payment

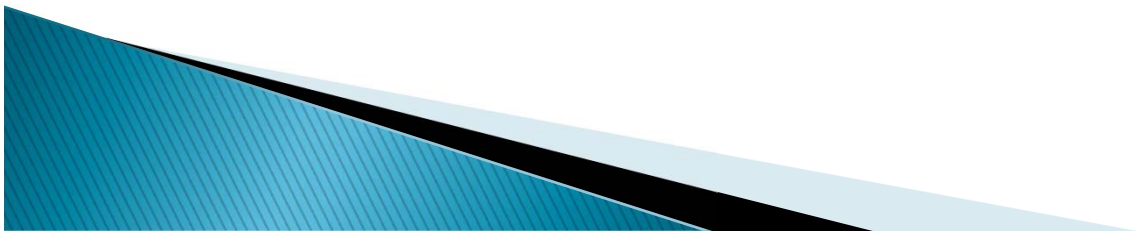
Revenue Enhancement Opportunities

- Implement measures to decrease chair time and increase turnover
  - Rapid infusion
    - Rituximab
    - Ipilumumab, pembrolizumab, nivolumab
    - Daratumumab
  - Subcutaneous formulations
    - Bortezomib (Velcade)
    - Rituximab (Hycela)
- Establish an institution/practice based specialty pharmacy operation
  - Offers many additional advantage



Revenue Enhancement Opportunities

- Utilize copay assistance program for patients with commercial insurance receiving standard of care therapies
  - Can increase profitability by collection of copays that may not have been collected previously
- Shift care to the outpatient setting
  - Inpatient chemotherapy use policy provides guidance on eligible regimens
- Provide alternate site of care options
  - Specialty Pharmacy/Home Infusion



University of Arizona Cancer Center

Transition of Inpatient Chemotherapy to Outpatient

- AML Regimens
  - HiDAC (high dose cytarabine)
  - 5+2 (cytarabine/Idarubicin)
  - Clofarabine
  - Clofarabine+HiDAC
  - MEC (mitoxantrone/etoposide/cytarabine)
  - ME
  - CLAG (cladaribine, cytarabine)
- ALL Regimens
  - HCVAD (cyclophosophamide/vincristine/doxorubicin/ dexamethasone)
- Lymphoma Regimens
  - EPOCH (etoposide/predinisone/vincristine/ cyclophosphamide/doxorubicin)
  - ESHAP (etoposide/methyprednisolone/cisplatin/cytarabine)
  - ICE (idarubicin/etoposide)
  - GIFOX (gemcitabine, ifosfamide/oxaliplatin)

Provided courtesy Ali McBride PharmD, MS, BCPS, BCOP
Clinical Coordinator Hematology/Oncology
Pending Publication in AJHP

Take Home Messages

- Be proactive with formulary process
  - Restrictions for use
  - Standardized ordering
  - Expedite addition to avoid non-formulary billing errors
- Develop guidelines for inpatient chemotherapy administration
- Develop formal process/policy for handling of off-label therapies
- Require precertification of all high cost medications and predetermination of off-label medications
- Utilize manufacturer assistance programs for uninsured/underinsured patients and for off-label support

Take Home Messages

- Invest in financial infrastructure to minimize write offs and maximize revenue
- Educate pharmacists, nurses, and physicians regarding reimbursement rules and differences between inpatient and outpatient reimbursement
  - Create realistic expectations with physicians
- Ensure personnel resources to implement cost containment strategies
  - Large systems should have single knowledgeable pharmacy leader to ensure consistency of all practices
- Pharmacy and Finance should work closely to implement strategies