Cost Containment Challenges and Strategies for Oncology Providers
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Objectives
- Describe challenges related to cost containment in the current healthcare environment
- Summarize the benefits of using compendia and other clinical information to streamline drug utilization and decrease drug expenditures
- Outline strategies for cost-containment; including the importance of dedicated staff
- Discuss strategies for minimizing write-offs and maximizing revenue

ABC News.com
July 29, 2010
Provenge® Cancer Vaccine: Can You Put a Price on Delaying Death?
By Courtney Hutchinson

- Can you put a price tag on the life of a prostate cancer patient?
- With the advent of sipuleucel-T (Provenge®) the first-ever vaccine cancer treatment, the tag has been set at about $23,000 per month of life gained of life gained -- $93,000 in total for a treatment that extends life, on average, by four months

CBS News.com
March 28, 2011
Some Inconvenient Facts About Yervoy®, Bristol-Myers' New "Holy Grail" Cancer Drug
By Jim Edwards

- After Bristol-Myers Squibb new “Holy Grail” cancer drug ipilimumab (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”
- But ipilimumab -- a fascinating new drug that boosts the body’s own immune system to attack cancer cells – was’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

The New York Times
October 14, 2012
In Cancer Care, Cost Matters
By Peter B. Bach, Leonard B. Saltz and Robert E. Wittes

- 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.
- That’s because ipilimumab is an injectable drug, and thus falls into the nonsensical legal loophole that requires federal programs such as Medicare/Medicaid to pay the full cost of the drug without negotiating price, simply because it’s a series of injections rather than pills.
- That price is one reason why Wall Street analysts expect ipilimumab to make $1.7 billion a year in revenues.
- The bottom line here is that the major cost of “R&D” cost of ipilimumab was nothing to do with the drug itself. It was the amount BMS paid to acquire the drug -- $2.1 billion.

Some Inconvenient Facts About Yervoy®, Bristol-Myers’ New “Holy Grail” Cancer Drug
By Jim Edwards

- That’s not the only inconvenient fact about 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 ipilimumab is an injectable drug, and thus falls into the nonsensical legal loophole that requires federal programs such as Medicare/Medicaid to pay the full cost of the drug without negotiating price, simply because it’s a series of injections rather than pills.
- That price is one reason why Wall Street analysts expect ipilimumab to make $1.7 billion a year in revenues.
- The bottom line here is that the major cost of “R&D” cost of ipilimumab was nothing to do with the drug itself. It was the amount BMS paid to acquire the drug -- $2.1 billion.

In the US, people spend almost 20% of the gross domestic product on health care, compared with about half that in most developed countries. Yet, in every measurable way, the results our health care system produces are no better and often worse than the outcomes in those countries.

The drag on our overall economy that comes with taxpayers, employers and consumers spending so much more than is spent in any other country for the same product is unsustainable. Health care is eating away at our economy and our treasury.

The Cancer Drug Profit Chain – By law, Medicare has to pay hospital’s 6% above what Congress calls the drug company’s “average sales price,” which is supposedly the average price at which the drug maker sells the drug to hospitals and clinics. But Congress does not control what drug makers charge. The drug companies are free to set their own prices. This seems to be fair in a free-market economy, but when the drug is a one-of-a-kind lifesaving serum, the result is anything but fair.

All the numbers tell one consistent story: Regulating drug prices the way other countries do would save tens of billions of dollars while still offering profit margins that would keep encouraging the pharmaceutical companies’ quest for the next great drug.

Through positive collaborations with Pharma, experts in chronic myelogenous leukemia (CML) have been fortunate to have 3 drugs approved by the FDA in 2012 for the treatment of CML: bosutinib, ponatinib, and omacetaxine. This is in addition to 3 others approved in the last decade, imatinib, dasatinib, and nilotinib. The 3 new drugs, however, have been priced at astronomical levels: ponatinib at $138,000 per year, omacetaxine at $28,000 for induction and $14,000 per maintenance course, and bosutinib at about $118,000 per year.

This Perspective reflects the views of a large group of CML experts, who believe the current prices of CML drugs are too high, unsustainable, may compromise access of needy patients to highly effective therapy, and are harmful to the sustainability of our national healthcare systems. These reflect the spiraling prices of cancer drugs in general. Of the 12 drugs approved by the FDA for various cancer indications in 2012, 11 were priced above $100,000 per year. Cancer drug prices have almost doubled from a decade ago, from an average of $5,000 per month to more than $10,000 per month.

How are the prices of cancer drugs decided? Of the many complex factors involved, price often seems to follow a simple formula: start with the price for the most recent similar drug on the market and price the new one within 10-20% of that price (usually higher).

As physicians, we follow the Hippocratic Oath of “Primum non nocere”, first (or above all) do no harm. We believe the unsustainable drug prices in CML and cancer may be causing harm to patients. Advocating for lower drug prices is a necessity to save the lives of patients who cannot afford them.

Challenges in the Current Healthcare Environment

- High cost medications
- Medications shortages
- Unfunded regulatory mandates
- Off-label medication use
- Restricted distribution
- Inventory and contract management
### Challenges in the Current Healthcare Environment

#### High cost medications
- Ado-Trastuzumab Emtansine (Kadcyla®)
  - Cost of therapy = $78,000 (11 cycles)
- Omacetaxine mepesuccinate (Synribo®)
  - Cost of therapy = $89,000 (6 cycles)
- Ziv-aflibercept (Zaltrap®)
  - Cost of therapy = $38,400 (6 cycles)
- Pertuzumab (Perjeta®)
  - Cost of therapy = $89,900 (17 cycles)
- Glucarpidase (Voraxaze®)
  - Cost of therapy = $112,500 (one treatment)

#### Brentuximab (Adcetris®)
- Cost of therapy = $216,000 (16 doses)

#### Ipilimumab (Yervoy®)
- Cost of therapy = $96,000 (4 doses)

#### Sipuleucel-T (Provenge®)
- Cost of therapy = $93,000 (3 infusions)

#### Eculizumab (Soliris®)
- Cost of therapy = $450,000 (annual per patient)
- Porfimer (Photofrin®)
  - Cost increase 7 fold price increase per vial = $37,200 for avg. dose

#### Medication shortages
- “Hoarding”
- Gray market price “gouging”
- Use of more expensive alternatives
  - Generic paclitaxel vs. Abraxane®

#### Unfunded regulatory mandates
- USP 797 requirements
- REMS program requirements

#### Off-label medication use
- Differing payer rules
  - Government
  - Commercial
- Various compendia
  - AHFS Drug Information®
  - Clinical Pharmacology
  - Micromedex®
  - NCCN Drugs and Biologics Compendium®

#### Restricted distribution
- Loss of volume credit
- Loss of wholesaler discount
- Credit checks
- Purchase orders
  - Multiple levels of approval
  - Multiple accounts

#### Inventory and contract management
- Multiple sites and inventories
- Class of trade, market share, rebates, and pricing

#### Personnel resources to manage all of the above!!

### Strategies to Overcome Challenges
#### High Cost Medications
- Develop high dollar chemotherapy process
  - Require pre-certification for high cost medications, especially new agents
  - Ensure insurance reimbursement
  - Identify patients in need of medication assistance
  - Inform patients of their financial obligation before treatment
- Started at the James Cancer Hospital with addition of sipuleucel-T (Provenge®) to Formulary
High Dollar Chemotherapy Process

- Pharmacy and Therapeutics Committee determines chemotherapy agents that should be managed via this process
- Includes medications where cost for treatment is > $50,000
- Current agents identified as high dollar
  - Ado-Trastuzumab Emtansine (Kadcyla®)
  - Omacetaxine mepesuccinate (Syne复®)
  - Eculizumab (Soliris®)
  - Brentuximab (Adcetris®)
  - Pertuzumab (Perjeta®)

No financial surprises

High patient satisfaction
- Aware of their financial obligation up front
- No financial surprises
- Feel like they have more control over their treatment
- Improved communication between finance staff and clinical team
- Tracking information emailed at least monthly to team
- Continual tracking of reimbursement
- Elimination of insurance denials
  - No insurance denials for sipuleucel-T (Provenge®) to date
Strategies to Overcome Challenges
High Cost Medications

- Require clinical evidence/compendia support for off-label indications
- Add to formulary with restrictions
  - Restrict to FDA-approved indications
  - Restrict to outpatient setting
    - Pegfilgrastim (Neulasta®)
    - Octreotide LAR (Sandostatin LAR®)
    - Denosumab (Xgeva®)
    - Modify inpatient dosing
    - Darbepoetin (Aranesp®)
- Pegfilgrastim (Neulasta®)
- Octreotide LAR (Sandostatin LAR®)
- Denosumab (Xgeva®)

Strategies to Overcome Challenges
High Cost Medications

- Require use of supportive care agents in clinical trials to follow institutional guidelines
- Rasburicase (Elitek®)
- Inventory management
  - Stock smaller vial sizes for medications that come as single dose vials (SDVs)
- Utilize 340B Purchasing
- Utilize pharmaceutical manufacturer medication assistance programs for uninsured/underinsured
- Oral chemotherapy, transplant, HIV medications
- Limited number of IV medications
  - Pegfilgrastim (Neulasta®), denosumab (Xgeva®), zoledronic acid (Zometa®), rituximab (Rituxan®), trastuzumab (Herceptin®), bevacizumab (Avastin®)
  - Note: Some of these IV assistance programs are NOT user friendly for large organizations
  - Aldesleukin (Proleukin®)
  - Melphalan (Alkeran®)
  - Round to the nearest vial size
    - Rituximab (Rituxan®)
    - Azacitidine (Vidaza®)
  - Minimize waste during sterile compounding
    - Leave SDVs in hood for up to 6 hours
    - Use PhaSeal™ to extend dating of SDVs up to 7 days
  - Coordinate/standardize administration times to minimize waste
  - Oral chemotherapy, transplant, HIV medications
  - Limited number of IV medications
  - Pegfilgrastim (Neulasta®), denosumab (Xgeva®), zoledronic acid (Zometa®), rituximab (Rituxan®), trastuzumab (Herceptin®), bevacizumab (Avastin®)
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  - Utilize co-pay foundations (i.e., disease-based assistance) for IV and oral high cost medications

Strategies to Overcome Challenges
High Cost Medications

- Standardize ordering
  - Comprehensive treatment plans
    - Pre-medications; supportive care medications
- Develop/ utilize treatment algorithms (e.g., NCCN)
- Shift care to the outpatient setting
  - HiDAC for consolidation
  - LHRH agonist in AMTU vs. BMT
  - Inpatient chemotherapy guidelines
- Preferred agents/therapeutic interchange
  - Leuprolide (Eligard®) vs. Goserelin (Zoladex®)
  - Panitumumab (Vectibix®) vs. Cetuximab (Erbitux®)

Strategies to Overcome Challenges
High Cost Medications

- 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 pharmacist to ensure compliance when receiving, handling, or dispensing medications
- Utilize pharmaceutical manufacturer medication assistance programs
  - Oral chemotherapy, transplant, HIV medications
  - Limited number of IV medications
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Strategies to Overcome Challenges

**Regulatory requirements**
- Decrease waste associated with USP 797 requirements by utilizing PhaSeal™ for drug vial optimization*.
- Develop policy and procedures to streamline implementation of REMS programs.
  - Integrate into current practice to the extent possible.
  - Clearly 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).

**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.

**Off-Label Medication Use**
- 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.
    - AHFS Drug Information®
    - Clinical Pharmacology
    - Micromedex® - Class I, IIa, IIb
    - NCCN Drugs and Biologics Compendium® - Category 1 or 2A.
  - Incorporate peer review and escalation of requests.

**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.

**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 pharmacists.
  - Accessing compendia, LCDs, NCDs.
  - Policy re-enforcement.

**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.
  - Cost sharing/co-pay assistance programs.
Medicare Process

Physician sees patient in clinic.

Treatment decision is made and includes off-label drug use. Physician discusses off-label risks with patient and documents in record.

If patient and physician decide to move forward with off-label use

Professional reviews supporting documentation for appeal if needed.

If patient and physician notified of need to sign Additional Beneficiary Notice (ABN),

If patient chooses to proceed:

Patient scheduled for treatment

Payer notifies Financial Counselor

Request to sign ABN

Appraiser reviews if needed:

If decision is upheld, MAP* entitled to begin referring to alternative assistance options. If no assistance available, refer patient case to CFO.

Commercial Payer Process

Physician sees patient in clinic.

Treatment decision is made and includes off-label drug use. Physician discusses off-label risks with patient and documents in record.

Patient and physician notified if need to sign Additional Beneficiary Notice (ABN).

If patient chooses to proceed:

Patient scheduled for treatment

Payer notifies Financial Counselor

Request to sign ABN

Appraiser reviews if needed:

If decision is upheld, MAP* entitled to begin referring patient to alternative assistance options. If no assistance available, refer patient case to CFO.

Strategies to Overcome Challenges

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

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
Strategies to Overcome Challenges
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
- Important to utilize EMR, decision support, policies and procedures, standardized orders to the extent possible
  - Assists with appropriate ordering of high cost medications, curbing off-label medication use, managing REMS program requirements

Strategies to Overcome Challenges
Personnel Resources

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

Strategies for Minimizing Write-Offs and Maximizing Reimbursement

- Be proactive with formulary process
  - Restrictions for use
  - Standardized ordering
  - Expedite addition to avoid non-formulary errors
- Educate pharmacists, nurses, and physicians regarding reimbursement rules and differences between inpatient and outpatient reimbursement
- Routinely review billing systems to ensure billing units and multipliers are correct
- Require pre-certification of all high cost medications and pre-determination of off-label medications

Strategies for Minimizing Write-Offs and Maximizing Reimbursement

- Develop guidelines for inpatient chemotherapy administration
- Work closely with payers and “ask for permission” in advance
- Work closely with Finance Department and hospital Medicare specialist
- Stay on top of changes in government and commercial payer policies
- Hire a dedicated pharmacy reimbursement specialist
- Involve pharmacists in review of denials

Strategies for Minimizing Write-Offs and Maximizing Reimbursement

- Establish a multi-disciplinary reimbursement committee
  - Review all high cost denials prior to write-off
  - Monitor actual vs. expected reimbursement for high cost medications
- Utilize manufacturer assistance programs for uninsured/underinsured patients and for off-label support

Questions?