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*NCCN Oncology Trends Reports  
Current Environment, Emerging  
Trends, and Future Directions*

# Managed Care & Medical Oncology

**“CANCER IS NOW ON THE TABLE”**

**Trish Goldsmith, Executive Vice President and Chief Operating Officer, NCCN**

**Jennifer Hinkel, MSc, Manager, Business Insights, NCCN**

July 15, 2009

# Learning Objectives

**At the conclusion of this program, participants will be able to:**

- List reasons why medical oncology is a new priority for managed care organizations
- Compare and contrast the historical methods for medical oncology reimbursement with current directions and trends
- Describe four key strategies or tools employed by managed care organizations to control utilization of cancer drugs and biologics

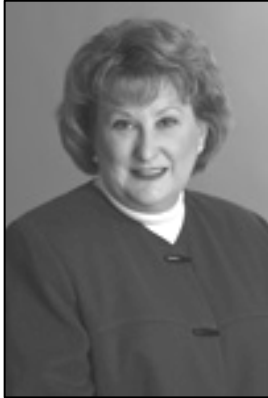


# Learning Objectives (continued)

- Identify examples of information sources and information products used by managed care organizations to drive coverage policy for drugs and biologics
- Define several emerging challenges to the status quo of managed care in medical oncology and describe how these might impact future coverage or reimbursement of cancer drugs and biologics
- Identify specific examples of how three of the largest managed care organizations in the U.S. are approaching medical oncology



# NCCN Presenters



**Trish Goldsmith, Executive Vice President and  
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National Comprehensive Cancer Network



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National Comprehensive Cancer Network



# Why is cancer “now on the table”?

- Population and demographic factors are leading to higher consumption of oncology services and products
- Targeted biologic agents are changing how cancer is treated and making cancer a chronic disease
- Payors are seeing an increase in “million-dollar cases,” even in high-incidence, “common” cancers
- Many of the proposed health care reforms may not apply well to oncology



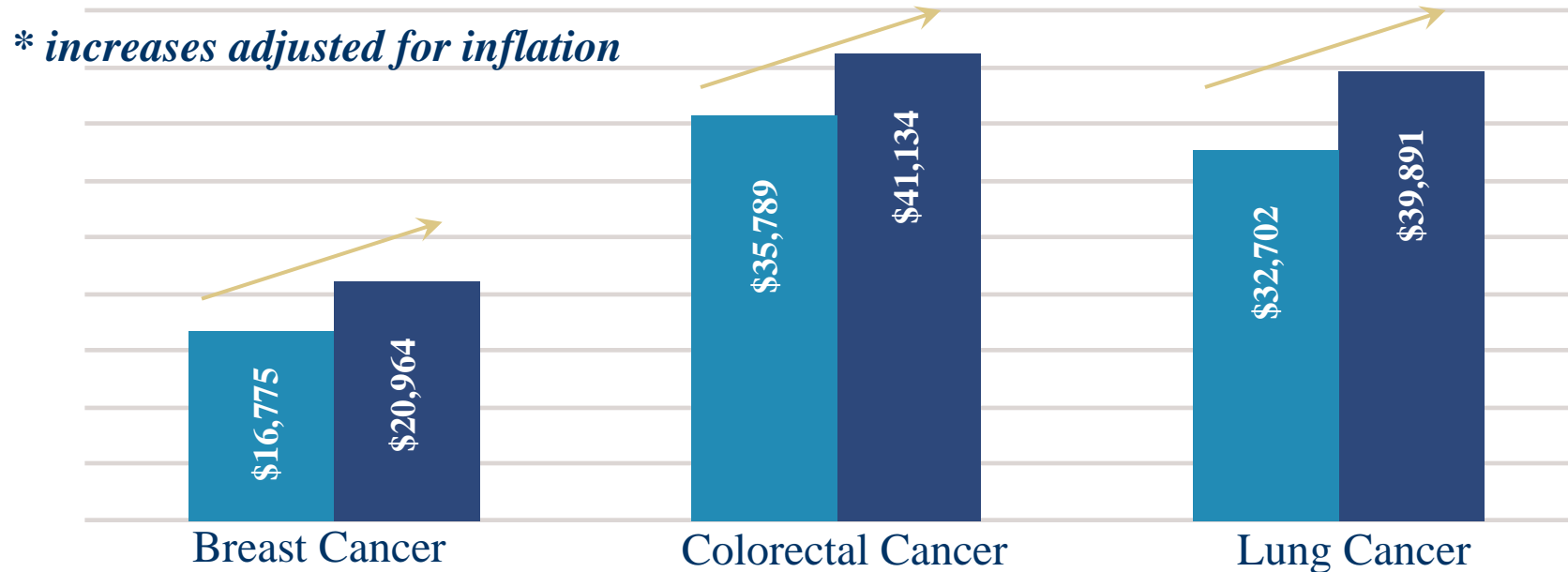
# Reviewing Cancer Prevalence, Incidence, and Cost of Treatment

- 1.437 million new cancer cases in 2008
- Estimated \$89.0 billion in direct medical costs in 2007, up from \$70 billion in 2005 <sup>1,2</sup>
- **Overall costs of cancer in 2007 are estimated to be \$219.2 billion once secondary costs of morbidity and mortality are included**

1. American Cancer Society. *Cancer Facts and Figures 2008*. Atlanta: American Cancer Society; 2008.
2. American Cancer Society. Costs of Cancer. Available at: [http://www.cancer.org/docroot/MIT/content/MIT\\_3\\_2X\\_Costs\\_of\\_Cancer.asp](http://www.cancer.org/docroot/MIT/content/MIT_3_2X_Costs_of_Cancer.asp). Accessed October 27, 2005.



# Initial Treatment Costs, 1991 and 2002



- **From 1991 to 2002, the average Medicare payments for initial treatment of the above three cancers rose by an average of 21%**
- **Some estimate that oncology costs are now rising at a rate of more than 20% per year**

Graphic adapted from data in Warren JL, Yabroff KR, Meekins A, Topor M, Lamont EB, Brown ML. "Evaluation of trends in the cost of initial cancer treatment." *J Natl Cancer Inst.* 2008 Jun 18; 100(12):889-97. Epub 2008 Jun 10.



# Recent data may underestimate rate of increase in cancer costs

- Medicare data up to 2002 does not include most oral anti-cancer agents (only covered after 2003 MMA)
  - Oral agents account for 50% or more of the current oncology pipeline
- Many high-cost agents have only come to market in recent years (e.g. bevacizumab, cetuximab)
- Recently developed agents are more likely to be additions to currently used regimens instead of replacements for existing treatment options

# Shifts in Oncologist Reimbursement

- **Past:** Reimbursement of parenteral agents at 95% of average wholesale price (AWP)
- **Present:** Shift to reimbursement based on average sales price (ASP) plus 6%
- **Private payors were initially slow to adopt this Medicare reimbursement model, but are increasingly adopting, or planning to adopt, ASP-based reimbursement methodologies**



# Why do payors see medical oncology as a priority?

- Cost implications of novel agents
- Oncology-heavy pharmaceutical pipelines
- Shift towards oral delivery of agents
- Mandates to measure quality and performance
- New reliance on information sources and emphasis on evidence

# Novel and New Agents

- Newer agents often have a high cost per dose
- Many agents are also delivered with a higher frequency of dose or longer duration of therapy
- **Result**: “Double Whammy” cost effect
  
- Some new agents are analogs of current or older treatments with similar mechanisms of action
- **Result**: Heftier price tags, but sometimes with improved therapeutic index and lower risk

# Oncology-heavy and Oral-heavy Development Pipelines

- Companies looking specifically at potential for biologic agents
- Currently fewer than 10% of antineoplastics are delivered orally, but 50% to 60% of oncology pipelines are oral formulations
- **Result**: Future agents likely to carry high prices, have reimbursement and distribution models specific to oral drugs, and have long time horizons before equivalents (“bio-similars”) are available on the market



# Mandates for Quality Measurement

- Managed care organizations are becoming increasingly reliant on data to drive decision-making and policy-setting
- Payors do not currently collect data at the level of specificity needed to assess quality of care in oncology
- Collaborations between payor organizations and clinical / provider organizations are closing this information gap



# Reliance on Information Sources

- Much of drug and biologic use in oncology is “off-label” (agents approved for one tumor type used for other tumor types based on available literature and evidence)
- Information sources such as drug compendia now allow managed care organizations to analyze patterns of off-label use and identify potentially inappropriate off-label prescribing



# Information Sources and Coverage Policy

- Key information sources include
  - Drug Compendia (various sources/publishers)
  - Federal data sources (CMS, FDA, AHRQ)
  - National Comprehensive Cancer Network
  - American Society of Clinical Oncology
  - ECRI Institute
  - Blue Cross and Blue Shield Association Technology Evaluation Center (TEC)
  - Hayes Health Technology Assessment & Consulting



# Key Compendia

- *NCCN Drugs & Biologics Compendium*<sup>TM</sup>
- Thomson Micromedex's *DRUGDEX* compendium
- American Hospital Formulary Service Drug Information (AHFS DI)
- Elsevier Gold Standard's *Clinical Pharmacology Compendium*
  
- **Extent to which various payors use compendia varies**
- **Only oncology-specific compendium is the *NCCN Drugs & Biologics Compendium*<sup>TM</sup>**



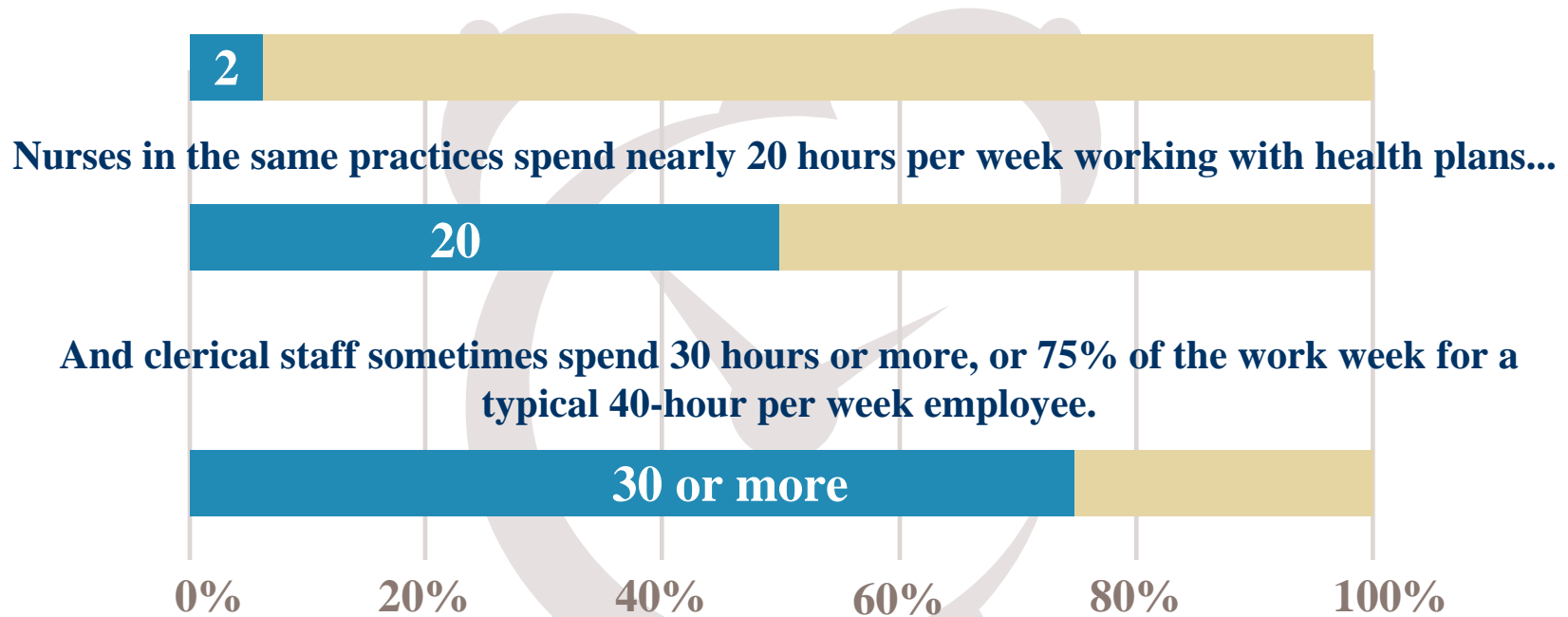
# Coverage Models and Mechanisms

- Precertification and Prior Authorization
  - Used by more than 75% of private payors to curtail potentially inappropriate use of drugs and biologics
  - Key targets are agents characterized both by high expense and wide variation and use
  - Supportive care (antiemetics, ESAs) often included
  - Time consuming activity for provider and payor



# Dealing with Coverage Issues Consumes Provider Time

**Specialty Physicians are spending 2 to 3 hours per week communicating with health plans on issues that include precertification for drugs and biologics.**



**Nurses in the same practices spend nearly 20 hours per week working with health plans...**

**And clerical staff sometimes spend 30 hours or more, or 75% of the work week for a typical 40-hour per week employee.**

*Graphic adapted from data in Casalino LP et al. "What Does it Cost Physician Practices to Interact with Health Insurance Plans?" Health Affairs. 2009 May 14;Web exclusive: w534.*



# Coverage Models and Mechanisms

- Payors are using formularies for supportive care, but the model does not necessarily apply to antineoplastic agents
  - Lists of drugs restricting coverage or lists that “tier” agents from the same class into categories, often on a cost basis
  - Uniqueness and lack of interchangeability of anti-cancer agents does not allow formulary use
  - Antiemetic drugs lend themselves to formulary management
  - Future shifts likely to be determined by clinical developments as more cancer drugs and biologics belong to similar classes (example: TKI inhibitors)



# Emerging Clinical Trends

- Increasing availability of oral therapies for cancer
- “Targeted Therapies” that interfere with or block specific molecular targets or pathways
- Increased understanding of biomarkers and how they can assist decision-making
- “Personalized Medicine” and pharmacogenomics maximizing outcomes for the individual



# Historical Perspective of Oral Agents

- **Pre-1980: primarily cytotoxic therapies**
  - Cyclophosphamide, methotrexate, procarbazine, chlorambucil ( ~10 agents total)
- **1980s – 1990s: primarily hormonal therapies**
  - Estramustine, anastrozole, raloxifene ( ~ 12 agents total)
- **2000s: primarily targeted therapies and immunomodulators**
  - Dasatinib, everolimus, lenalidomide, lapatinib, sorafenib, vorinostat, erlotinib, sunitinib, nilotinib, imatinib, thalidomide ( 15 or more agents)



# Implications of Oral Pipeline

- Oral therapies are usually managed through a pharmacy benefit rather than a medical benefit
- Oral coverage governed by different mechanisms than parenteral coverage
- Results in strange incentives that may encourage providers to use parenteral therapies even when they cost more

# Targeted Therapies

- Targeted therapies block growth and division of cancer cells
- Targets could be specific proteins or enzymes, growth factors, or processes needed by cancer cells to divide, grow, or spread
- Include TKIs, drugs inducing apoptosis, monoclonal antibodies, angiogenesis inhibitors, hormone receptor modulators, etc.

# Biomarkers

- Specific variations in tumor genetics or makeup
- May have predictive value for prognosis or response
- Identify sub-populations of patients that may be more or less likely to benefit from a given intervention
- Include hormone receptors, her-2-neu receptor, KRAS, PSA



# Challenges to the Status Quo

- Specialty Pharmacy distribution models
- Comparative Effectiveness as a “buzzword”
- “Value-Based Insurance Design” (VBID)
- Negotiating for lower drug prices

# Specialty Pharmacy

- Program used by pharmacy benefit management (PBM) organizations to control distribution of drugs
- May employ a closed method of distribution
- Potential to threaten revenue stream for oncology pharmacies within hospitals
- Unanswered questions regarding specialty pharmacy's ability to address safety and adherence challenges with oral agents

# Comparative Effectiveness

- Sometimes mistakenly or deliberately confused with “cost-effectiveness”
- Existing CE paradigms may not be applicable to cancer treatment
- Difficult lessons learned abroad (United Kingdom’s NICE and kidney cancer agents)



# Value Based Insurance Design

- Rooted in theory that some interventions are more “valuable” than others
- Proponents espouse a benefit design that incentivizes consumers to choose interventions with higher value
- Administratively complex to implement, especially in oncology



# Negotiating Drug Prices

- Concept that CMS as a bulk purchaser could negotiate directly with pharma/biotech for lower prices
- Proponents cite international models (UK, Canada) and Veteran's Administration
- Even abroad, drug price negotiation is only one component of price controls for pharmaceuticals
- CMS discussing “least costly alternative,” but authority of CMS to pay in this manner remains in question

# Cost Sharing in Oncology

- Implications for clinical (and financial) outcome
- “Grade 4 Financial Toxicity”
- As outcome may hinge on adherence, high co-payments or out-of-pocket costs are a disincentive to continue therapy

# Quality Evaluation of Cancer Care

- MCOs have a growing interest in quality evaluation
- Often payors do not have enough specific data (tumor stage, patient status) to assess quality in cancer
- Payor/provider collaborations are emerging to help measure delivered care against existing recommendations, guidelines, and pathways
- Example: NCCN collaborating with Ingenix to develop a quality tool for several high-incidence malignancies



# Payor Perspectives

- Lack of consensus over how precertification and prior authorization should apply to cancer drugs/biologics and whether “pay for performance” can be applied to oncology
- Most are using NCCN Drugs & Biologics Compendium™
- One payor identified a “trust gap” between patients and payors
- Reimbursement for infusion drugs is a target, but approaches vary
- Payors are feeling the crunch of economic and system-wide issues, such as the rise in uninsured and COBRA patients





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