

# Accessing Pharmaceuticals through Medicare: Part B versus Part D

**American Public Health Association Conference  
2007**

**Washington DC, USA**

**November 7, 2007**

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November 7, 2007

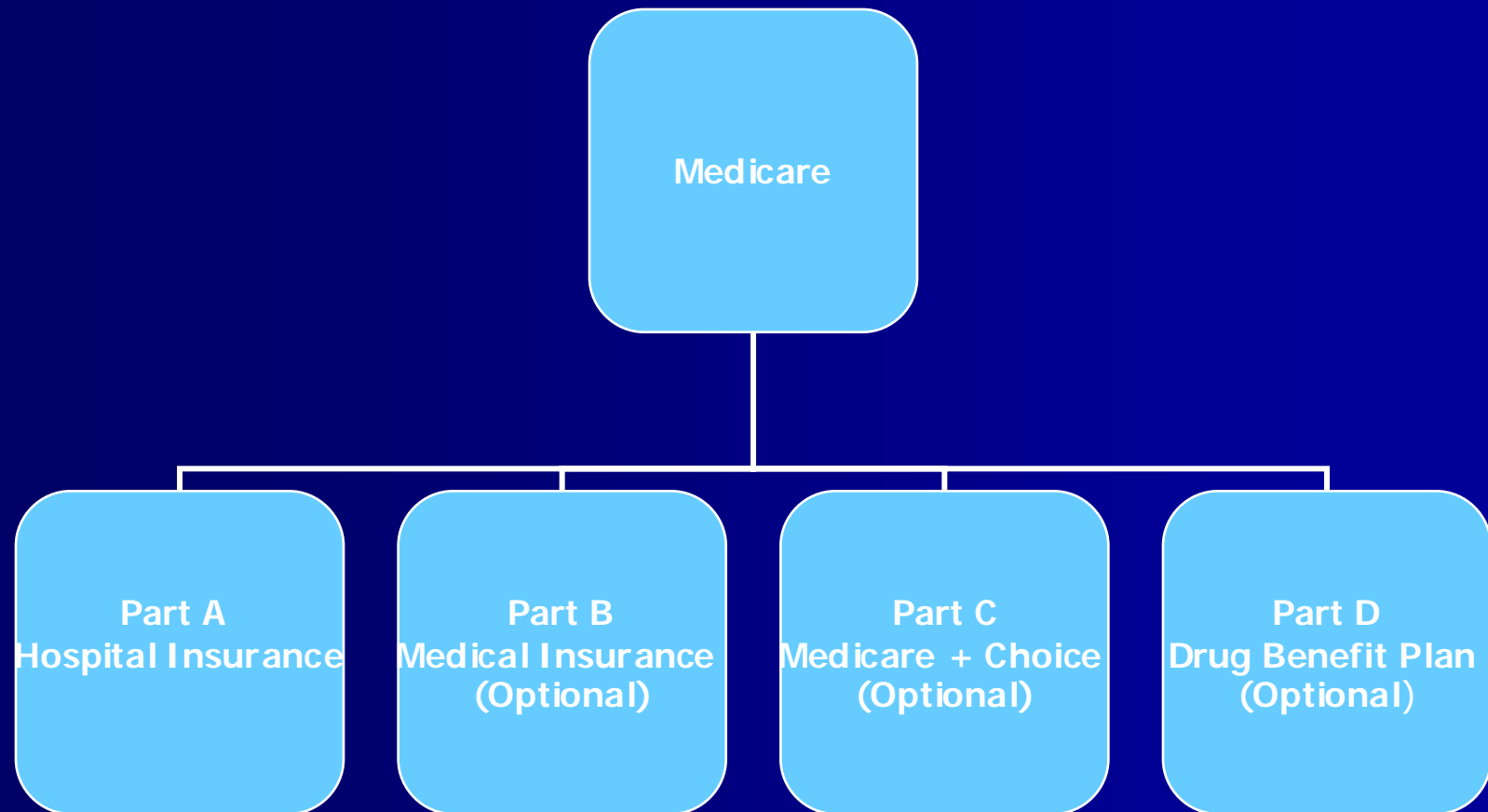
# Learning Objectives

- Differentiate between Medicaid Part B and D prescription benefits
- Identify situational rules for determining coverage by Part B and/or Part D
- Apply the situational rules in determining coverage for a oral antiemetic drug and a new prophylactic vaccine.
- Recognize the implicit dilemmas present in trying to provide continuity of patient care within these programs

# Overview

- Medicare
  - Part B Basics
  - Part D Basics
- Dual Eligible
- Situational Rules
- University of Texas M.D. Anderson Experience
  - Aprepitant
  - HPV vaccine
- Conclusions

# Medicare Components



# Covered Entities



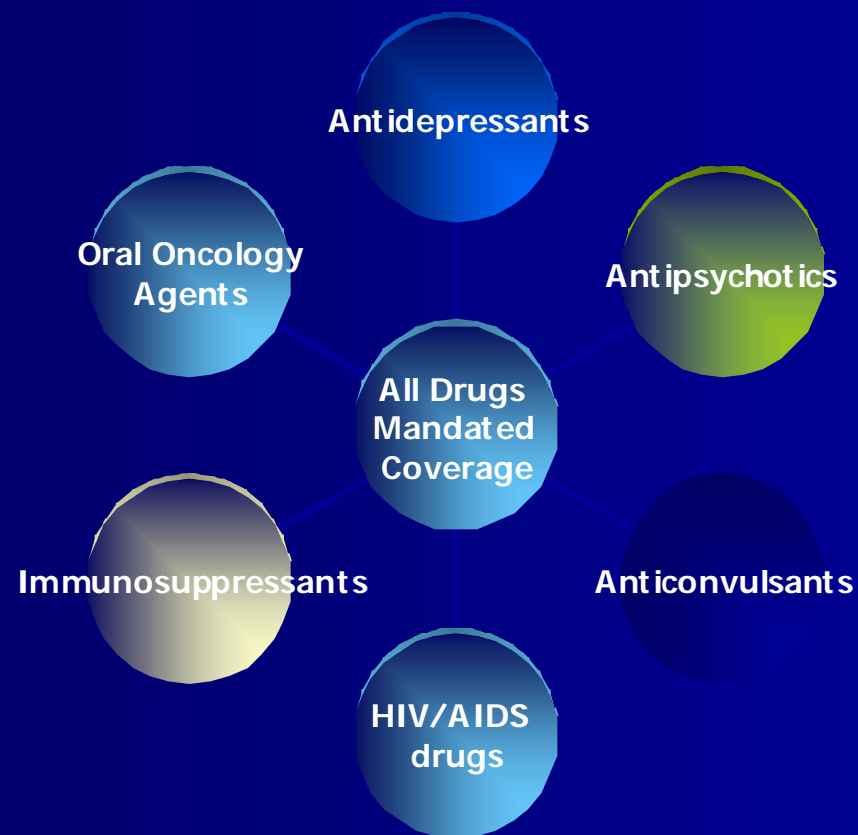
# Medicare Part B Drug Coverage

- Drugs prescribed and dispensed by physicians
- Drugs prescribed and administered by physicians
- Usually limited to drugs or biologicals administered by infusion or injection
- Drugs used in select circumstances by pharmacy suppliers (e.g. use with DME)
- Drugs billed from treatment facilities for ESRD
- Decision of coverage made by local administrator usually.

# Medicare Part D Drug Coverage

- An outpatient/retail prescription benefit program
- No National Formulary
- United States Pharmacopeia (USP) developed guidelines that identified 146 unique therapeutic categories and classes.
- Include at least 2 drugs from each category
- Can appeal to cover non-formulary and off-label utilization (if listed in 1 of 3 compendia)
  - The American Hospital Formulary Service (AHFS) drug information
  - The United States Pharmacopoeia Drug Information (USP-DI)
  - The DRUGDEX information system

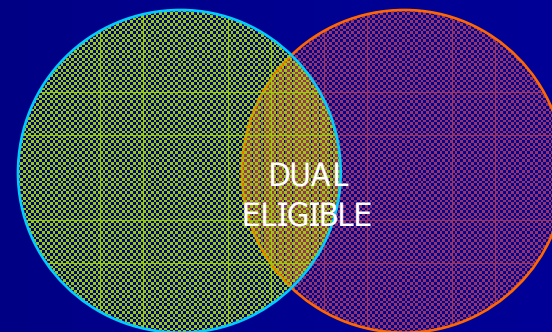
# Part D Drug Coverage





# Dual Eligible

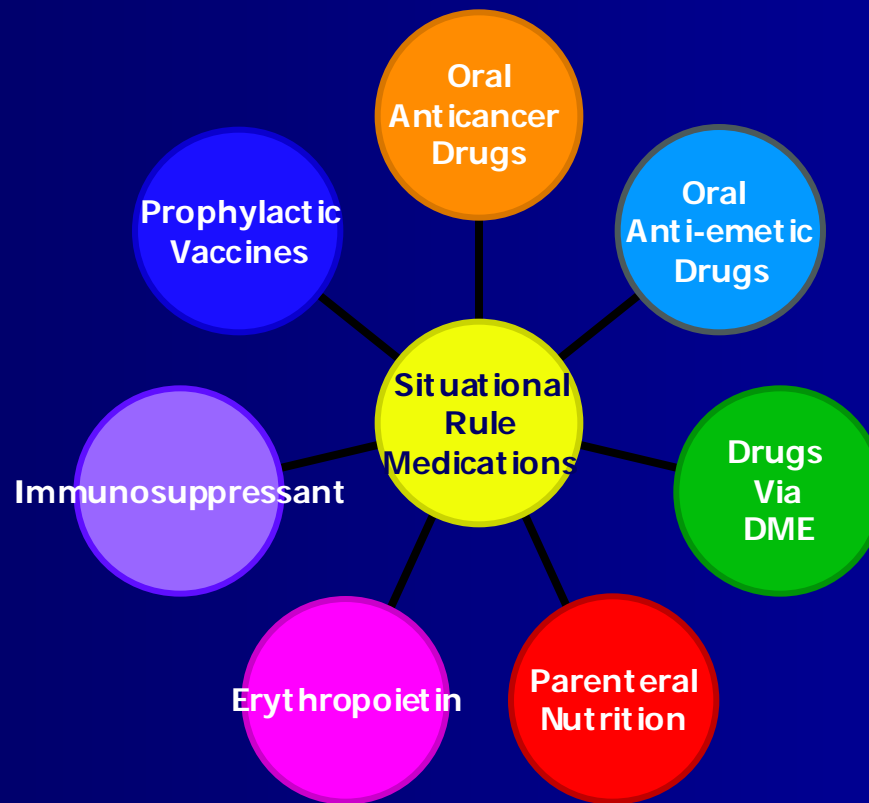
- Some drugs excluded from Part D (Nine classes)
- However, cannot discriminate the dual eligible
- Over-the-counter medications: Part of Step-therapy program.
- Barbiturates and Benzodiazepines: Cannot abruptly withdraw
- Drugs can be covered under Part A, Part B, Part D, or Medicaid



# Situational Rules for Coverage (B vs. D)

- Type of drug/ingredient
- Patient's place (type) of residence
- Where or when patient received a medical procedure utilizing the medication
- Time (duration) of administration
- Type of pharmacy setting
  - Retail or home infusion pharmacy
  - Long term care pharmacy

# Drugs with Situational Rules



# Oral Anti-Emetic Drugs

- PART B Coverage Description:
  - Oral anti-emetic drugs used as full therapeutic replacement for IV anti-emetic drugs within 2 hours prior and 48 hours post chemotherapy regimen.
  - Aprepitant will be covered when used as part of a three-drug oral anti-emetic regimen (dexamethasone + 5-HT<sub>3</sub> receptor antagonist) with level 5 chemotherapeutic regimen.
- PART D Coverage Description:
  - All other situations, including after 48 hours of chemotherapy regimen.
  - Aprepitant will be covered when used as an anti-emetic in other situations, including other levels of chemotherapeutic regimen.

# Prophylactic Vaccines

- PART B Coverage Description:
  - Treatment: Vaccines specifically for a direct injury or exposure
  - Prophylaxis: Influenza, Pneumococcal, and Hepatitis B (for intermediate to high risk)
- PART D Coverage Description:
  - All other medically necessary vaccines

# The University of Texas M. D. Anderson Cancer Center (MDACC)

## MDACC Description

- Comprehensive cancer center
- Not-for-profit
- Organized into multidisciplinary specialty centers
- Culture

## Patient Population

- 50% of patients on investigational protocol
- All cancers, all payment systems

## Staff

- 800 physicians
- 200 pharmacists
- 1700 nurses

## Volume

- 512 bed hospital
- 2,500 outpatient visit/day

## Drug Budget

- \$250 million dollar drug budget for FY08
- Pharmacy accounts for 12% of expenses
- **Provides 30% of revenue**

# Aprepitant

- FDA Indication:

- Prevention of acute and delayed nausea and vomiting associated with highly-emetogenic chemotherapy in combination with a corticosteroid and 5-HT<sub>3</sub> receptor antagonist

- Dosing:

- Oral: 125 mg day 1, followed by 80 mg on days 2 (48hours post) and 3 (72hours post)

# Aprepitant: Actual Usage Patterns (9/1/2006-3/31/2007)

Area	Number of Patients (N=1388)
Inpatient	377
Ambulatory Treatment Center (ATC)	486
Outpatient	525
<b>65 and over (All 3 areas)</b>	<b>265</b>
<b>65 and over Medicare (All 3 areas)</b>	<b>173</b>



# Aprepitant: Actual Reimbursement Patterns for Elderly Medicare Patients ( $\geq 65$ years) (9/1/2006-3/31/2007)

Plan	Number of Patients	Average Charge to Reimbursement Rate
Part A (Inpatient)	59	Bundled
Part B (ATC)	70	27%
Part D (Outpatient)	44	??????

# Dispensing Patterns for Aprepitant Prescriptions for 72 hours of therapy

Per Chemo Session	IP RX (#) (Part A)	ATC RX (#) (Part B)	OP RX (#) (Part D)
Scenario 1	1(1tab)	1(1tab)	1(1tab)
Scenario 2	2 (1tab each)		1(1tab)
Scenario 3	3 (1tab each)		
Scenario 4		1(1tab)	1(2tab)
Scenario 5		2(1tab each)	1(1tab)
Scenario 6		3(1tab each)	
Scenario 7			1(3tab)
Scenario 8			1(6tab)

# Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine (HPV)

## ■ FDA Indication:

- Females: Prevention of cervical cancer, genital warts, cervical adenocarcinoma *in situ*, and vulvar, vaginal, or cervical intraepithelial neoplasia caused by human papillomavirus (HPV) types 6, 11, 16, 18 in 9-26 year olds.

## ■ Dosing:

- I.M.: Females: Children  $\geq 9$  years and Adults  $\leq 26$  years: 0.5 mL followed by 0.5 mL at 2 and 6 months after initial dose

# Formulary Evaluation – Economic Model: Patient Population

- Female patients at MDACC during 2005 were grouped according to age (N = 18,280)
  - Vaccinate only patients covered by FDA indications (females 9-26)
  - Vaccinate all female patients (females 9-105)
  - Vaccinate all female patients who test HPV negative (females 9-105)

# Formulary Evaluation – Economic Model - Assumptions

- Estimates of numbers of patients positive for human papilloma virus (HPV) in each age group were taken from Burchell et. al. (Vaccine 2006; 24 Suppl 3:S52-61 ).
- Male patients and female patients younger than 9 were excluded.
- Costs:
  - Three 0.5 ml doses (MDACC purchased cost) \$120
  - Clinic visit (FAC, facility fee) \$229
  - Nurse visit/injection \$120
  - HPV test \$800

# Formulary Evaluation – Economic Model – Budget Impact

Age group	Vaccinate all in age group \$\$	Vaccinate HPV negative in age group \$\$
9-26 (FDA)	1,115,652	1,666,049
9-105	21,191,553	32,443,698
27-105	20,288,295	30,777,649

# HPV Vaccine: Actual Usage Patterns (9/1/06- 3/31/07) (N=36)

Area	Number of Unique Patients	Number of Prescriptions
Inpatient	3	3
Ambulatory Treatment Center	29	32
Outpatient	4	4

# HPV Vaccine: Actual Usage Patterns (N=36)

Elements	Number of Patients
Female Patients 9-26 years of age	29
Female Patients >26 and <65 years of age	5
Female Patients $\geq$ 65 years of age	0
Male Patients	2



# HPV Vaccine: Billing Patterns (N=36)

Plan	Number of Patients
CASH	3 (including 2 males)
Blue Cross	19
Commercial	1
Free Care	1
HMO	1
Champus	1
Medicare Part B	1 (27 year old female patient in ATC)
PPO	6
None Indicated	3

# Anticipated Policy Changes -2008

- National Comprehensive Cancer Network (NCCN) Drug Compendia will be approved for Medicare decisions regarding cancer treatments.
- Medicare Part D can now cover both the vaccine product and the vaccine administration, starting in 2008.
- Aprepitant IV coming up for FDA approval at end of 2007 or early 2008.

# Methods to Decrease Confusion

- Indicate on the prescription the following:
  - Diagnosis
  - Indication
  - Place of administration
  - Part B or Part D coverage
  - Advance Beneficiary Notice (ABN)

# Conclusions

- Tracking and administering the situational rules for coverage is quite time-consuming and intricate.
- CMS approach to fixing these problems appears to be incremental in nature, one drug at a time.
- Possibility of affecting continuity of care in patients is high.
- Quality waste possibility high in situational coverage.

# References

- <http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Download/PartBandPartDdoc>07.27.05.pdf>
- <http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/PartDPolicyTechReg.pdf>
- Kilian J, Stubbings J. Medicare Part D: Selected Issues for Pharmacists and Beneficiaries in 2007. J Manag Care Pharm. 2007;13(1):59-65.
- Piper KB. Navigating Medicare Drug Coverage: Part B vs. Part D. Manag Care. 2006 Jul;15(7 Suppl 3):17-20.

# THANK YOU

- ***MORE INFORMATION:***

- *www.medicare.gov*

- *Call 1-800-MEDICARE*

