Generic Substitution
in Medicare Part D Plans

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Credits and Notes

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  - Henry J. Kaiser Family Foundation
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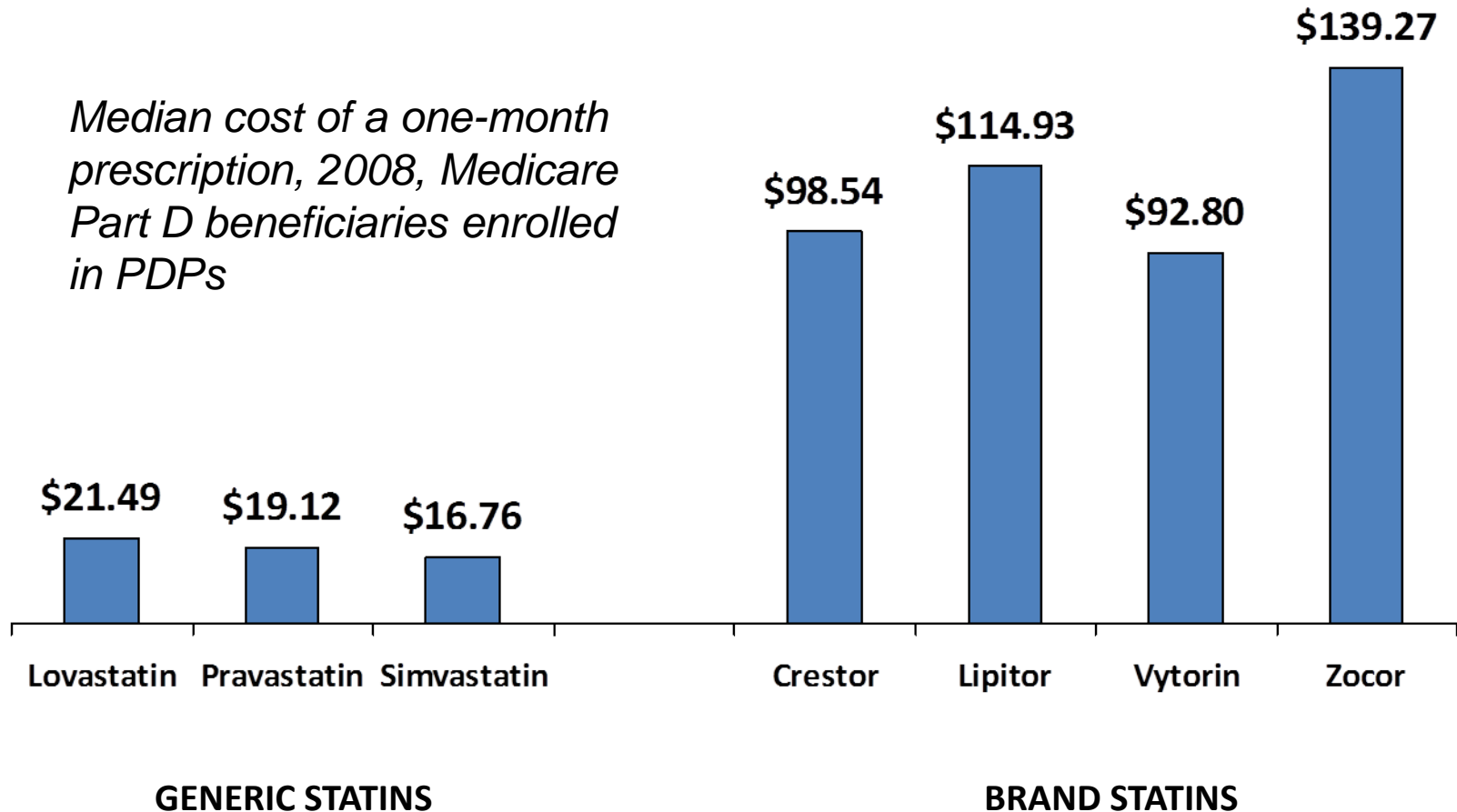- **Links to our full reports: hpi.georgetown.edu/medicarepartd**

Presentation Objectives

- Identify the most important factors by which drug plans maximize use of generic drugs by plan enrollees

- Estimate the share of generic drug use for Medicare beneficiaries

Why Generic Use Matters

- **In most cases, generic use should be a win-win, generating savings**
  - Lower beneficiary costs
  - Lower government costs
- **As well as the potential for better health**
  - Individuals are more likely to continue taking their medications
  - Possible better outcomes
  - But adherence can vary by drug class
- **CBO: Generic use reduced 2007 costs by $33 billion**
  - 55 percent higher spending if no generics available

Generic Statins are Cheaper than Brand Statins

Median cost of a one-month prescription, 2008, Medicare Part D beneficiaries enrolled in PDPs

GENERIC STATINS:
- Lovastatin: $21.49
- Pravastatin: $19.12
- Simvastatin: $16.76

BRAND STATINS:
- Crestor: $98.54
- Lipitor: $114.93
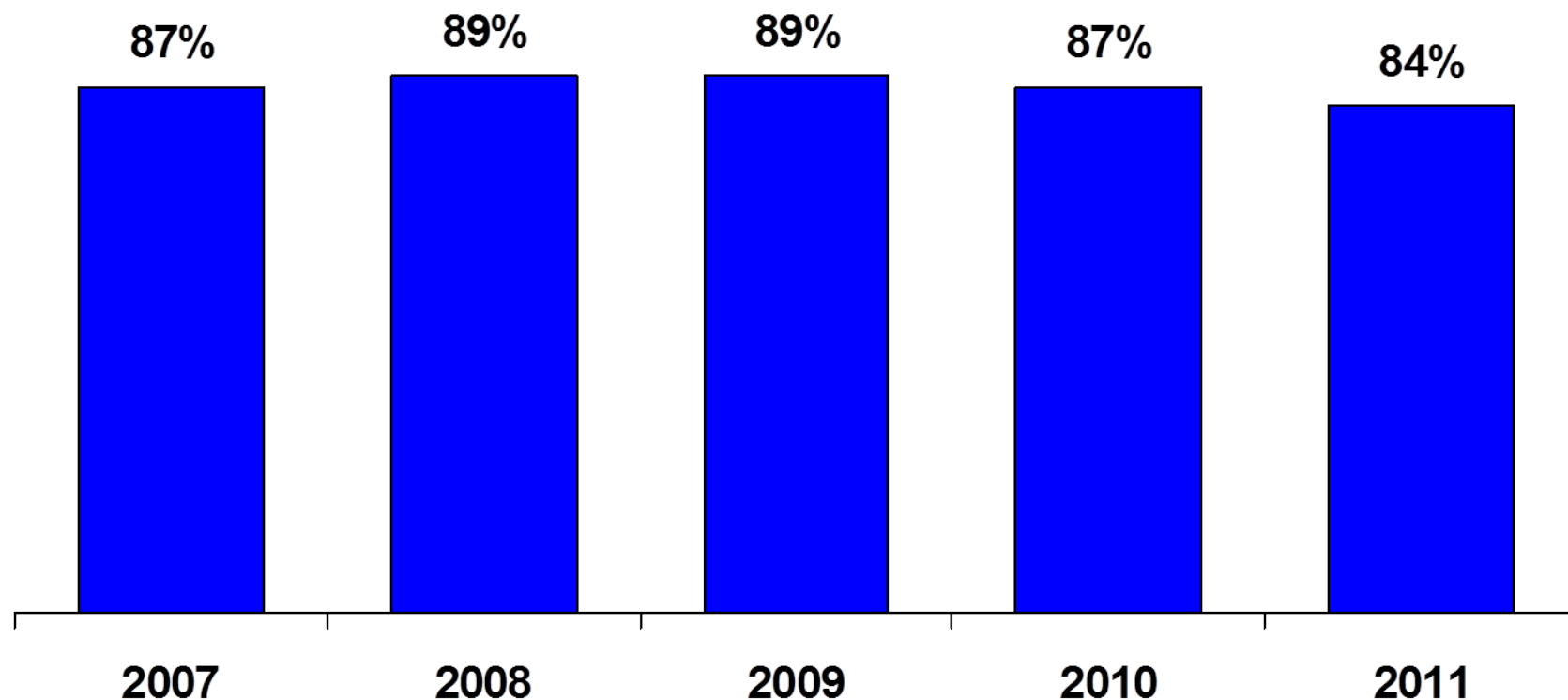- Vytorin: $92.80
- Zocor: $139.27

SOURCE: Hoadley et al. analysis of Medicare prescription drug events data, 2008.

Part D Plan Strategies to Encourage Generic Use

- **Exclude some brand drugs from the formulary**
- **Apply tiered cost sharing**
- **Utilization management**
  - Prior authorization
  - Step therapy

- **Generic use varies by plan: 54% to 76%**
  - CMS reported data, 2008

Share of Drugs on Formulary, PDPs, 2007-2011

Percentage of All Chemical Entities

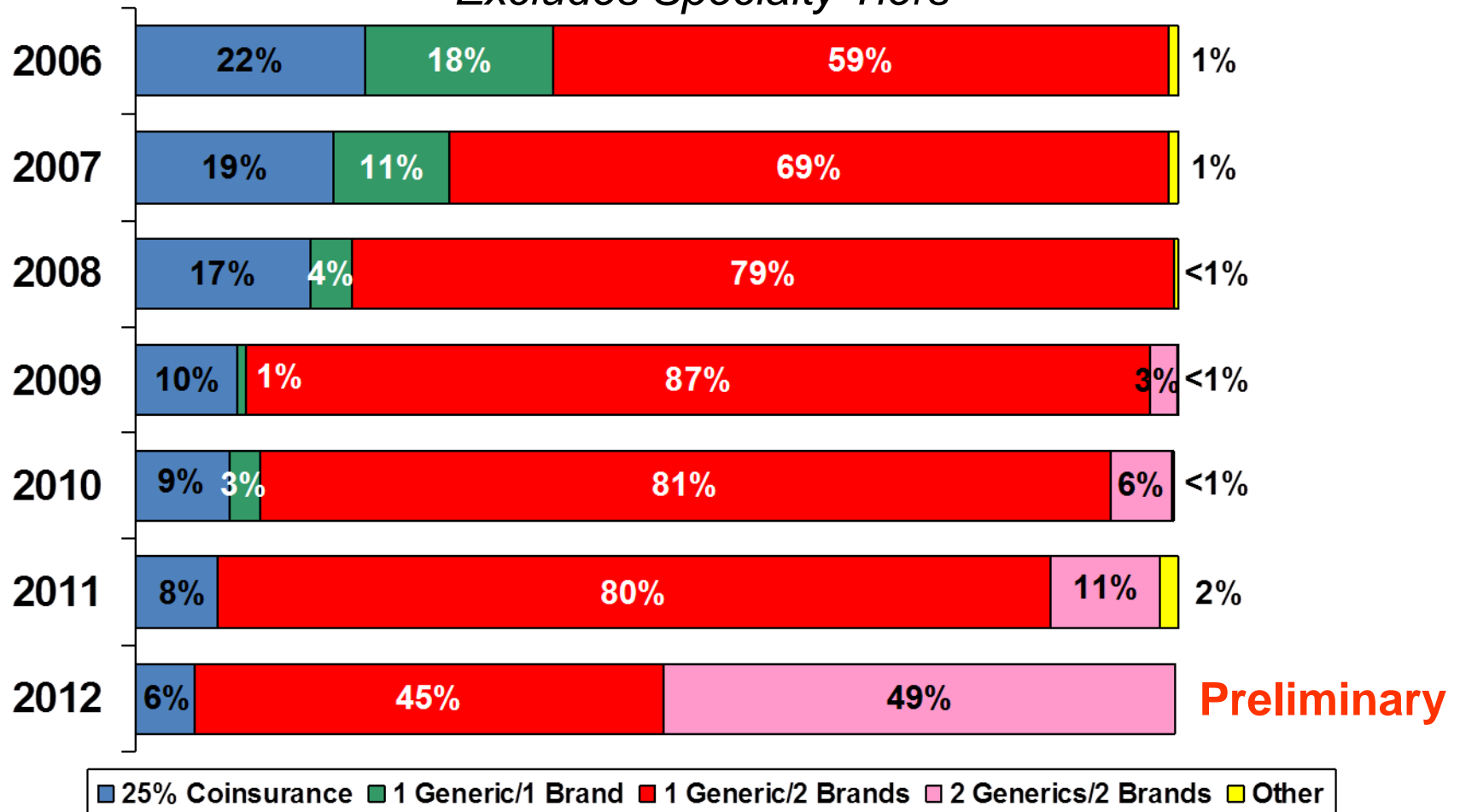| Year	Percentage
2007	87%
2008	89%
2009	89%
2010	87%
2011	84%

NOTE: Calculations are shares of all chemical entities, weighted by enrollment. Ns are numbers of chemical entities based on the analysis of the CMS reference file for this project.

SOURCE: Hoadley et al. analysis of CMS formulary files for MedPAC
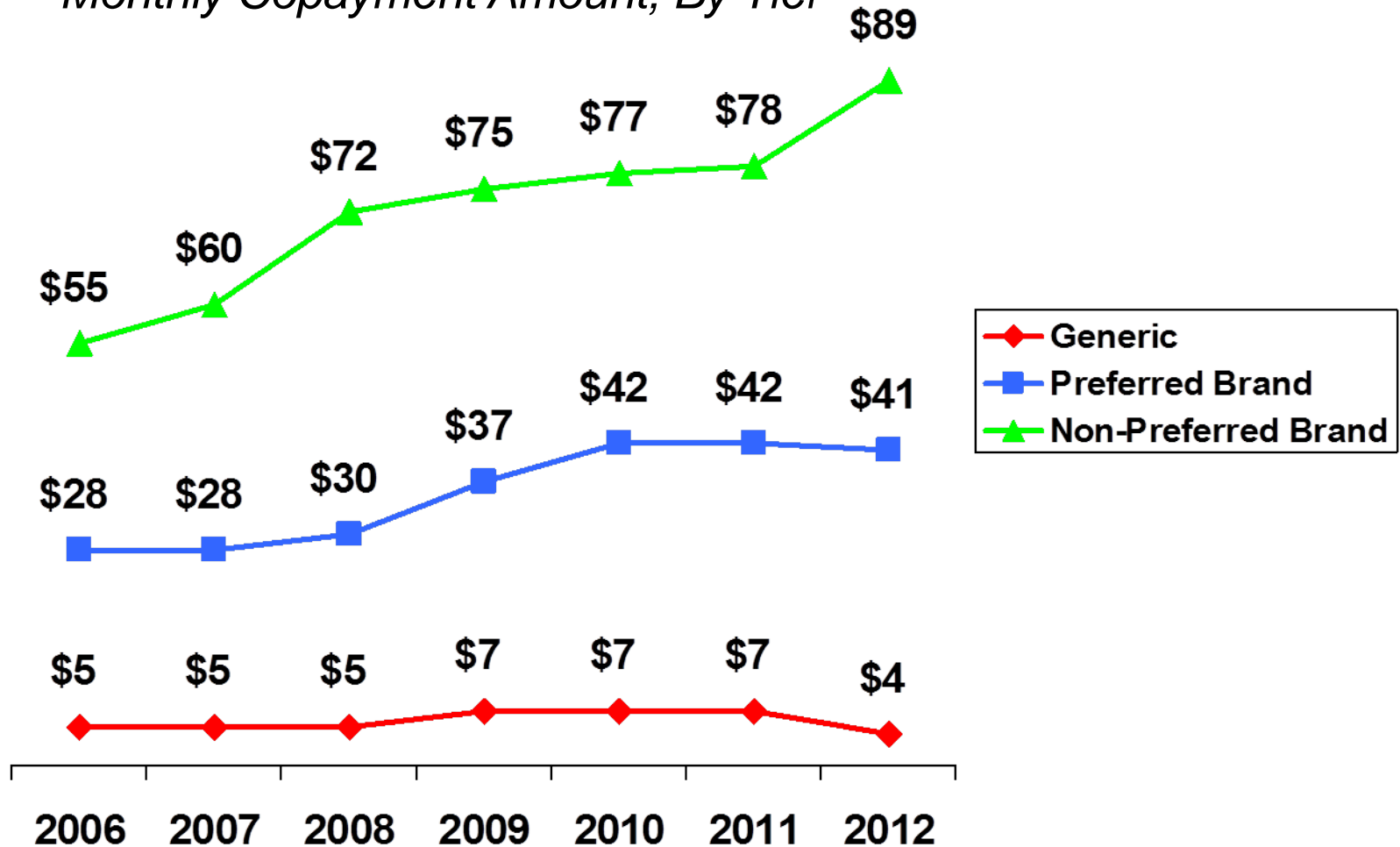
Cost-Sharing Tier Structures, PDPs, 2006-12

Share of Plans, Weighted by Enrollment
Excludes Specialty Tiers

Year	25% Coinsurance	1 Generic/1 Brand	1 Generic/2 Brands	2 Generics/2 Brands	Other
2006	22%	18%	59%		1%
2007	19%	11%	69%		1%
2008	17%	4%	79%		<1%
2009	10%	1%	87%	3%	<1%
2010	9%	3%	81%	6%	<1%
2011	8%		80%	11%	2%
2012	6%		45%	49%	**Preliminary**

Legend: ■ 25% Coinsurance ■ 1 Generic/1 Brand ■ 1 Generic/2 Brands ■ 2 Generics/2 Brands ■ Other

NOTE: Calculations are share of plans, weighted by enrollment. Most non-standard plans also use specialty tiers, shown in a separate chart. Tracking of 2 generics/2 brands formularies began in 2009; some "other" plans before 2009 had that structure.
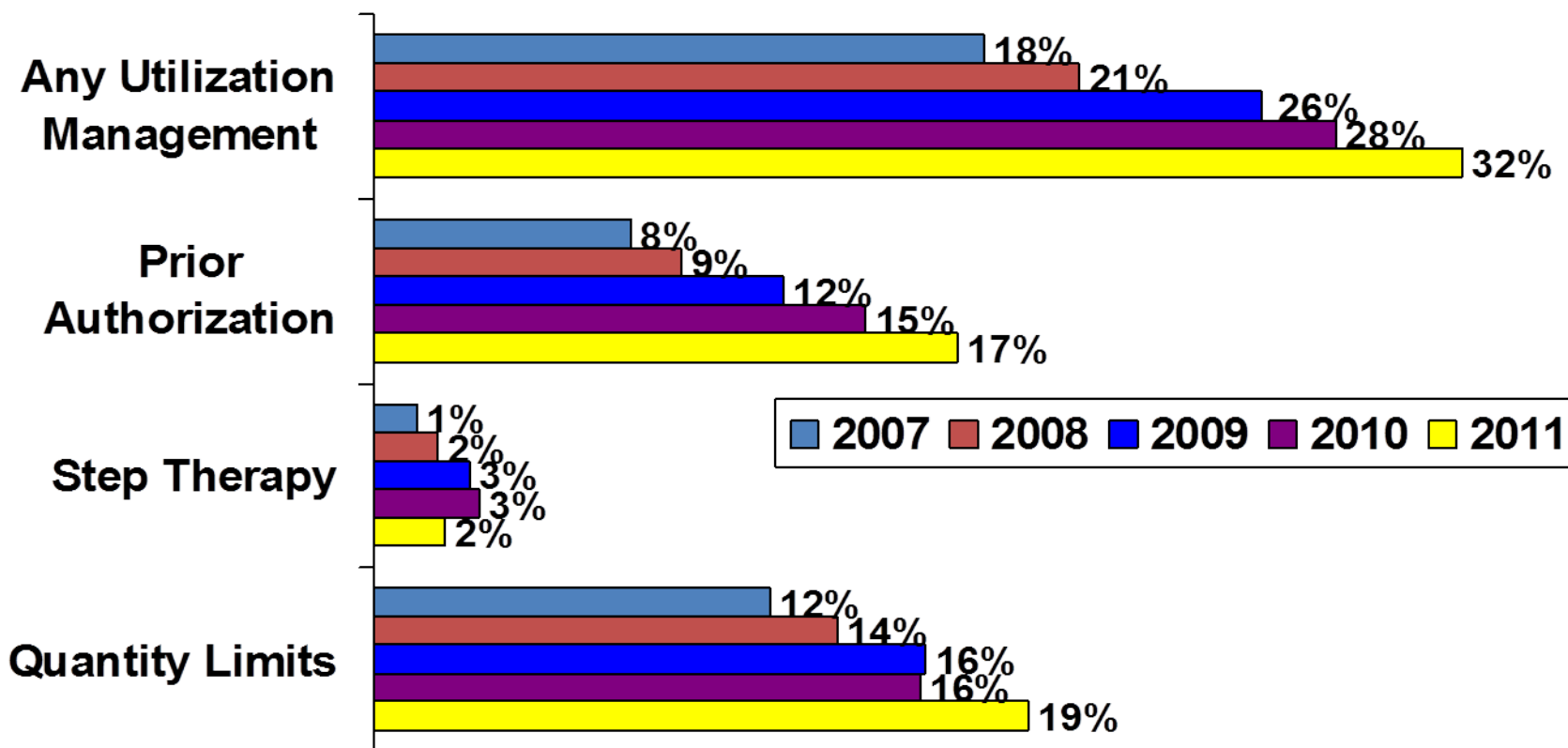
Copayment Trends, PDPs, 2006-2012

Monthly Copayment Amount, By Tier

Non-Preferred Brand: $55, $60, $72, $75, $77, $78, $89

Preferred Brand: $28, $28, $30, $37, $42, $42, $41

Generic: $5, $5, $5, $7, $7, $7, $4

Legend:
- Generic (red)
- Preferred Brand (blue)
- Non-Preferred Brand (green)

Years: 2006, 2007, 2008, 2009, 2010, 2011, 2012

SOURCE: Hoadley et al. analysis of CMS formulary files for MedPAC

Share of Drugs with Utilization Mgmt, PDPs, 2007-2011

Average Share of Drugs Listed on Formulary

NOTE: Calculations are share of listed chemical entities, weighted by enrollments.

SOURCE: Hoadley et al. analysis of CMS formulary files for MedPAC

Literature Findings

- **Adherence is higher for generics than brands in 6 classes: 59% to 52%**
  - Shrank et al., 2006
- **Adherence is higher and outcomes modestly better for statins and hypertension drugs for people with cardiac history**
  - Choudhry et al. 2011
- **Larger brand-generic copay difference affects generic dispensing rate**
  - O'Malley 2006, Mager & Cox 2007 AJMC, Kamal-Bahl 2004, Landon 2007

Research Questions

- **Is generic use within a drug class influenced by benefit or formulary design?**

- **Do effects vary by drug class?**
  - Different generic alternatives and rules
  - Varying plan policies in different classes
  - Beneficiary, prescriber willingness to switch drugs

- **Does impact of plan design differ for Low-Income Subsidy (LIS) vs. non-LIS beneficiaries?**
  - Law requires lower cost sharing

Focus on Therapeutic Substitution

- **Choice among alternative medications in same drug class**
    - Not just the same chemical entity
- **Slower rate of change than straight generic substitution**
- **Requires new prescription**
    - Unlike generic substitution where pharmacist may switch
- **Willingness to substitute varies across drug classes**

Model

- **Dependent variable:**
  - Was individual's last Rx of year in this class generic?
- **Primary independent variables:**
  - Plan's copay for generics in class
  - Plan's copay for brands in class (separate variables for popular brands)
  - Plan's use of step therapy, prior authorization in class
- **Controls:**
  - Individual drug use: use of generics, overall use
  - Individual characteristics: age, race, urban/rural
  - State policies on generic substitution
  - State of residence
- **Repeat by drug class, LIS status**

Data

- **2008 Part D prescription drug event data**
  - 20 percent sample
- **Included:**
  - Beneficiaries age 65 and over, enrolled in a stand-alone PDP, who had at least one prescription in the selected class
- **Excluded:**
  - Beneficiaries not in a single plan all year, died during year, in Medicare solely based on ESRD, or resident of the territories
- **LIS and non-LIS addressed in separate models**

Defining Generic Use: Statins

- **Total in sample taking a statin:**
  - 710,000 non-LIS and 399,000 LIS beneficiaries
- **Last drug used was generic: 58%**
  - Most use only generics during the year
  - A few start with a brand and end with a generic
- **Most statin users have stable use: 89% use same drug all year**
- **Adherence is higher for generics**
  - 61% of those using generics versus 53% for brands
- **Median days supply for year = 270 days**

SOURCE: Hoadley et al. analysis of Medicare prescription drug events data, 2008.

Statin Market, Part D, 2008

Drug	Percent of Statin Users	Median Full Price (30 days)	Mean Copay (30 days)
Generics			
SIMVASTATIN	41%	$17	$5
LOVASTATIN	9%	$21	$5
PRAVASTATIN	10%	$18	$4
Common Brands (all on-patent)			
Lipitor	30%	$115	$34
Vytorin	9%	$93	$38
Crestor	9%	$100	$47
Other Brands (9 drugs, including off-patent)			
All other brands	3%	$117	$68

NOTE: Mean copay is defined as copay faced by plan enrollee; includes full price in those plans where drug is off formulary.

SOURCE: Hoadley et al. analysis of Medicare prescription drug events data, 2008.

Independent Variables: Plan Characteristics

Independent Variable	Mean
Cost Sharing Variables	
Generic copay	$5.15
Brand copay for Lipitor	$33.57
Brand copay for Crestor	$46.90
Brand copay for Vytorin	$38.44
Brand copay for Other Brands	$67.54
Utilization Management (Requirement for any brand in class)	
Prior authorization	27.3%
Step therapy	62.0%
Other Plan Variables	
Plan premium	$35.82
Plan deductible	$59.07
Standard plan (25% coinsurance)	9.8%
No gap coverage	83.9%
Presence of a generic not on G tier	1.9%

SOURCE: Hoadley et al. analysis of Medicare prescription drug events data, 2008.

Independent Variables: Enrollee Characteristics

Independent Variable	Mean
Drug utilization characteristics	
Total days supply, other drugs	1,346
Share of days generic, other drugs	68.6%
Share of days DAW, statins	1.6%
Share of days DAW, other drugs	4.8%
Share of days 90-day supply	39.0%
Demographic characteristics	
Age 65 to 74	47.4%
Original entitlement, other than age	6.5%
Female	63.1%
White	94.8%
Urban	48.3%
State laws, for state of residence	
Mandatory substitution	28.5%
Dispense as written must be written out	49.2%
No requirement for patient consent	14.5%

SOURCE: Hoadley et al. analysis of Medicare prescription drug events data, 2008.

Likelihood that Last Statin Filled in 2008 is Generic

Independent Variable	Odds Ratio for Higher Generic Rate	Confidence Interval
Generic Copays (Compared to $0 copay)		
$1-4		
$4-6		
>$6		
Brand Copays (Effect of additional $10)		
Lipitor		
Crestor		
Vytorin		
Other Brands		
Utilization Management (Requirement for any brand in class)		
Prior authorization		
Step therapy		

* Statistically significant at .05 level.

SOURCE: Hoadley et al. analysis of Medicare prescription drug events data, 2008.

Comparing Different Plans

Predicted Share of Generic Statin Use, by Plan, 2008, Non-LIS Enrollees Over Age 65

Plan	Generic Copay	Lipitor Copay	Crestor Copay	Other Brand Copay	Prior Auth	Step Therapy	Predicted Generic Use
A	$0	$115†	$99†	$126†	No	No	--%
B	$0	$34	$30	$126†	No	Yes	--%
C	$7	$30	$75	$75	No	No	--%
D	$10	$43	$99†	$126†	Yes	No	--%
E	$7	$24	$24	$93	No	No	--%

† Full cost because drug is off formulary for this plan.

SOURCE: Hoadley et al. analysis of Medicare prescription drug events data, 2008.

Antidepressant Market, 2008

Drug	Percent of Antidepressant Users	Median Full Price (30 days)
Generics		
Sertraline	22.7%	$13.35
Citalopram	16.4%	$10.33
Paroxetine	13.4%	$20.00
Fluoxetine	12.5%	$8.00
Common Brands (all on-patent)		
Lexapro	17.3%	$83.16
Cymbalta	7.5%	$118.33
Effexor	7.1%	$120.09
Other Brands (including off-patent)		
All other brands	1.3%	$117.60

SOURCE: Hoadley et al. analysis of Medicare prescription drug events data, 2008.

Comparing Antidepressants to Statins

- **Preliminary results**
- **Weaker relationships overall**
  - Weak relationship to generic copays: partly in direction opposite to hypothesis
  - High brand copays associated with higher generic use
  - Significant effect for prior authorization and step therapy, but opposite to hypothesis
- **Why?**
  - Less willingness to substitute drugs?
  - Protected class under CMS guidelines?

Low-Income Subsidy Beneficiaries

- **Much reduced copay levels**
  - Variations for different LIS categories
  - 2008 values: $1.05/$2.25 generic vs. $3.10/$5.60 brand
- **Little room for plan variation in copay levels**
  - But small differences add up for users of multiple drugs
- **Plan tools include:**
  - Leave drugs off formulary (increasing copay to full cost)
  - Prior authorization and step therapy
- **Question of whether available tools can influence generic use for LIS beneficiaries**

Summary of Results

- **Cost sharing and utilization management both associated with increased generic drug use**
- **Effect of both tools appears to differ by class**
  - Different results for statins and antidepressants
- **Potentially different results for LIS enrollees**

Limitations

- **No claims for off-formulary purchases**
- **Selection effects**
  - Individuals who want to continue taking a brand may have selected their plans based on generous coverage of brands
- **Other plan strategies to encourage generics, not measured in drug claims data**
  - Mailings, financial incentives
- **Intermediary role of physician**
- **No ability to control for beneficiary income**

Impact on Spending

- **Plan designs that increase generic use can yield savings**
- **Savings are shared by government, enrollees, drug plans**
- **Factors limiting potential savings**
  - Changes in patent status already happening
  - Unwillingness of some patients, prescribers to make therapeutic substitutions

Cost Implications: Statin Use

- **Potential Medicare savings based on model** (based on 2008 drug use patterns)
  - X% increase in generic statin use would yield $X in reduced cost (shared by government, enrollees, plans)
- **Some savings will start occurring through availability of generic Lipitor**
  - Unless coupons or other policies intervene
- **No clinical advantage for Crestor over Lipitor could encourage therapeutic substitution**

Cost Implications Beyond Statins

- **Savings may not be available in all classes**
  - Antidepressants and other mental health drugs
  - HIV, cancer, specialty drugs
- **Other "substitutable" classes may yield savings**
  - ACE inhibitors and ARBs for hypertension
  - Proton pump inhibitors
  - Osteoporosis drugs
  - Diabetes (Actos and Avandia)

Implications for Part D

- **Generic substitution already a large part of keeping Part D's costs lower than expected**
- **Policy tools to increase generic use**
    - Mandate more effective benefit designs
    - Encourage best practices (e.g., bonuses, performance measures)
    - Strengthen market incentives for plans (e.g., less reinsurance, risk sharing)
- **Need to accommodate drug class differences?**
- **Different policies for low-income enrollees?**

Future Research

- **How do results for other drug classes compare to statins and antidepressants?**
  - Hypothesis: in many drug classes (like statins), therapeutic substitution is viewed favorably and has support from literature
  - Hypothesis: in a few drug classes (like antidepressants), less willingness to substitute
- **What influences are effective for LIS enrollees?**
  - Possible role of $0 copay
  - Impact of utilization management
  - Education about generic drug use

Assessment Question #1:

Based on the presented analysis, which is the most important factor to maximize use of generics?

A. Allow full flexibility for physicians to prescribe drugs they prefer

B. Set a $0 copayment for generic drugs

C. Place some brand drugs on a preferred and others on a non-preferred tier

D. Require prior authorization for brand-name drugs

Assessment Question #2:

What share of prescriptions for Medicare beneficiaries were filled as generic drugs in 2008?

    A. 32%

    B. 54%

    C. 69%

    D. 88%