



# Generic Substitution in Medicare Part D Plans

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## Credits and Notes

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# Presentation Objectives

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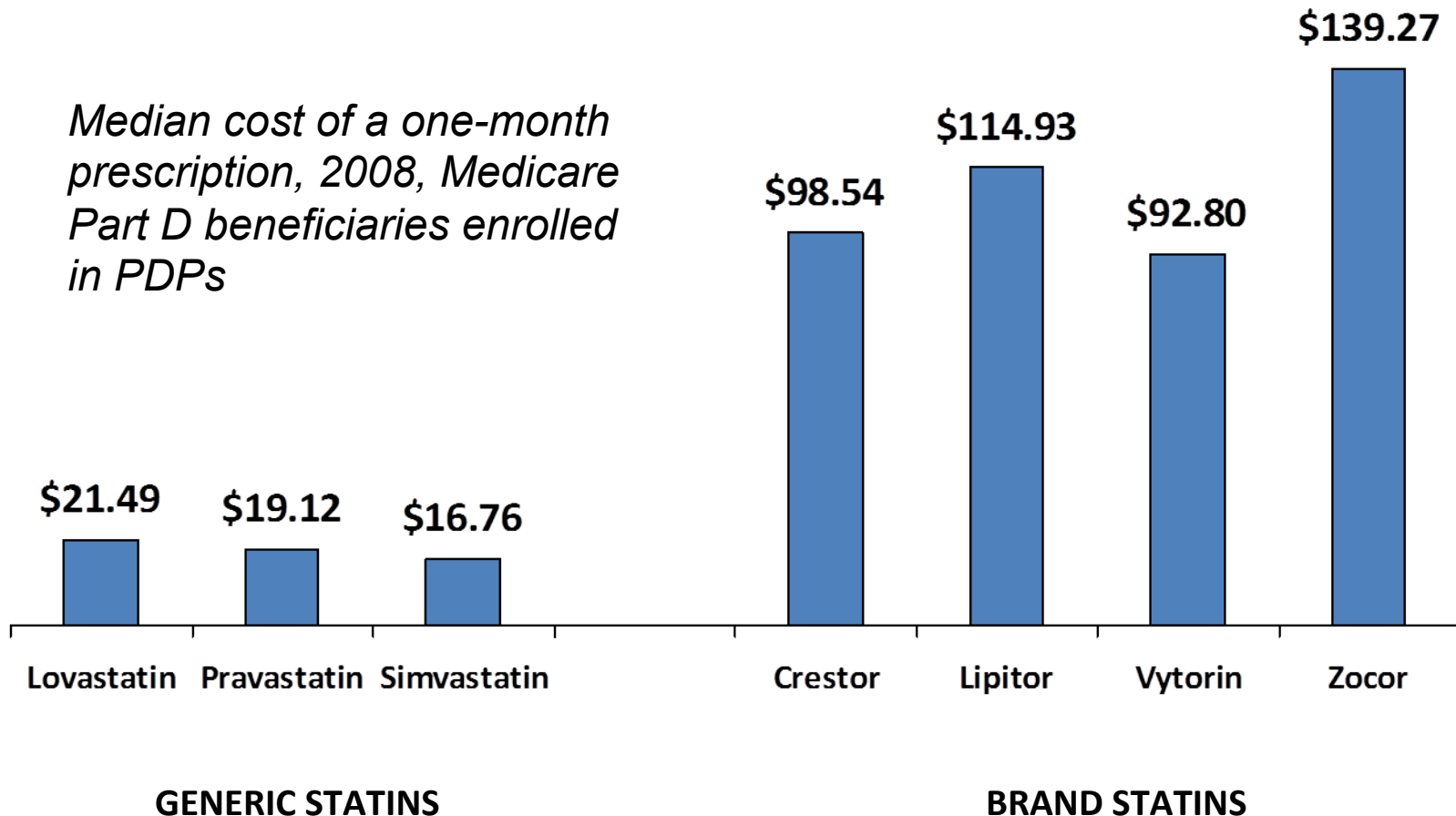
- Identify the most important factors by which drug plans maximize use of generic drugs by plan enrollees
- Estimate the share of generic drug use for Medicare beneficiaries

# Why Generic Use Matters

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- **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



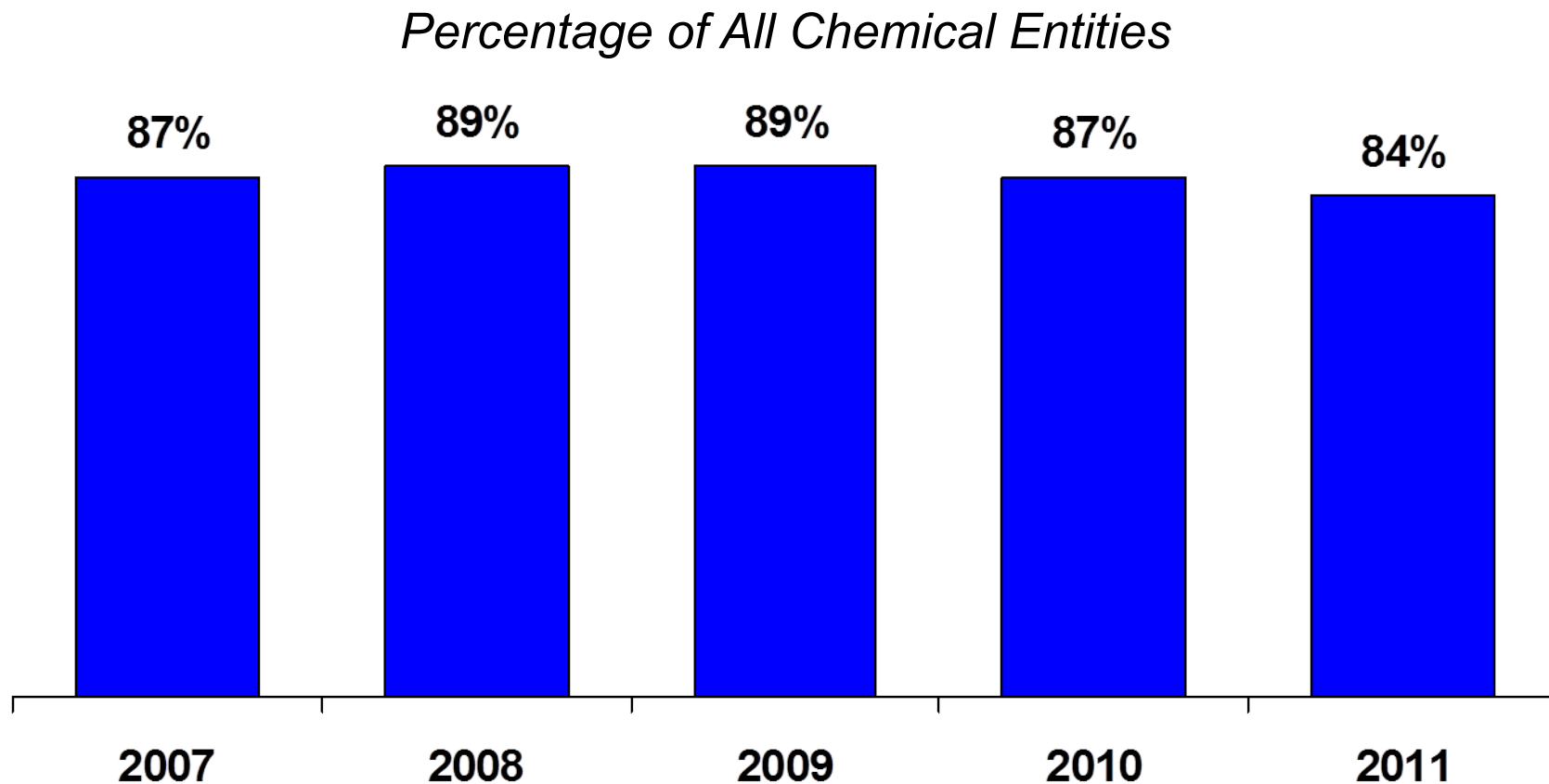
SOURCE: Hoadley et al. analysis of Medicare prescription drug events data, 2008.

## Part D Plan Strategies to Encourage Generic Use

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- **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

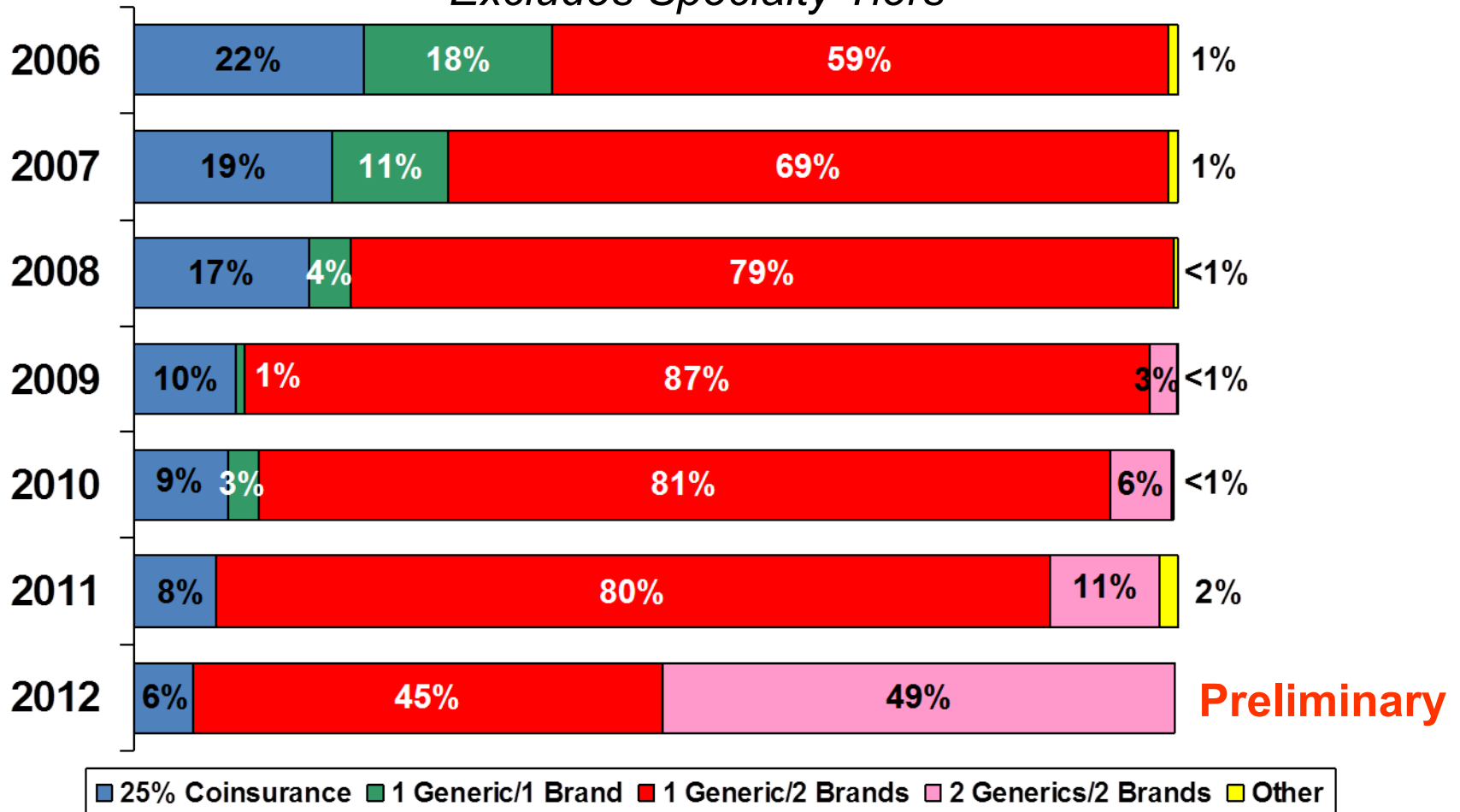


NOTE: Calculations are shares of all chemical entities, weighted by enrollment. Ns are numbers of chemical entities based on the analysis of the CMS reference file for this project.

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*

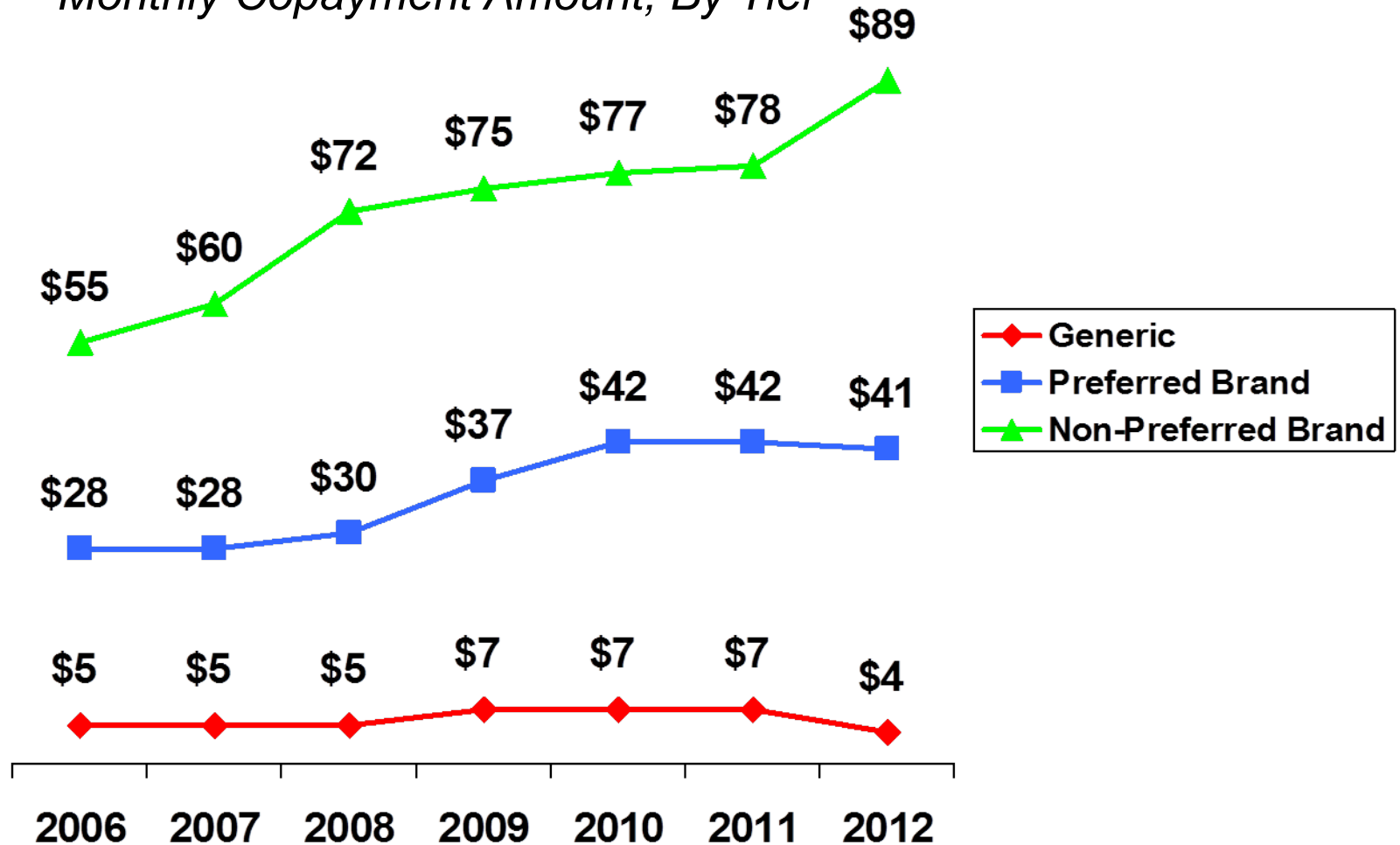


NOTE: Calculations are share of plans, weighted by enrollment. Most non-standard plans also use specialty tiers, shown in a separate chart. Tracking of 2 generics/2 brands formularies began in 2009; some "other" plans before 2009 had that structure.



# Copayment Trends, PDPs, 2006-2012

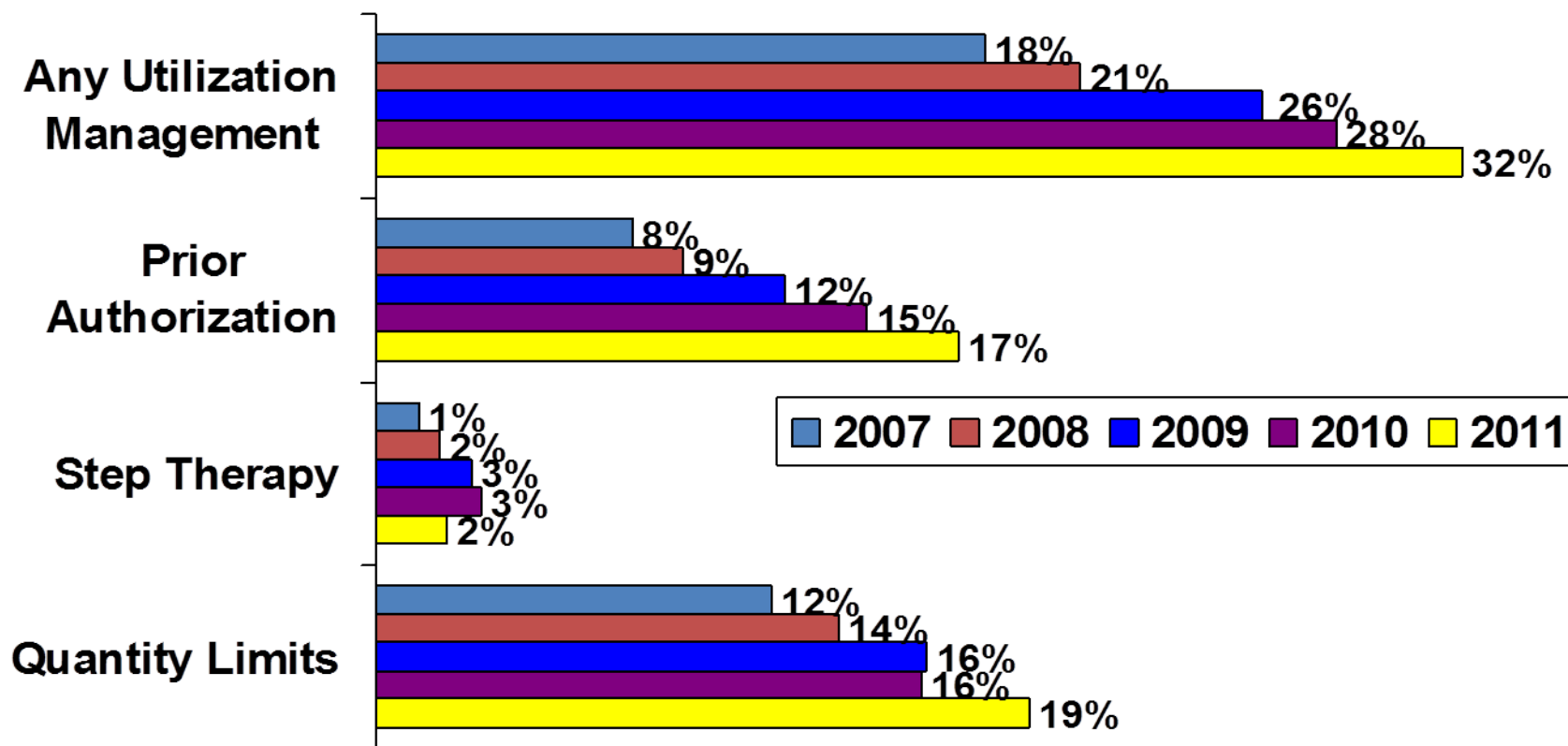
*Monthly Copayment Amount, By Tier*



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

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- **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

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- **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

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- **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

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- **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**

- **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

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- **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)
<b>Generics</b>			
SIMVASTATIN	41%	\$17	\$5
LOVASTATIN	9%	\$21	\$5
PRAVASTATIN	10%	\$18	\$4
<b>Common Brands (all on-patent)</b>			
Lipitor	30%	\$115	\$34
Vytorin	9%	\$93	\$38
Crestor	9%	\$100	\$47
<b>Other Brands (9 drugs, including off-patent)</b>			
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
<b>Cost Sharing Variables</b>	
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
<b>Utilization Management (Requirement for any brand in class)</b>	
Prior authorization	27.3%
Step therapy	62.0%
<b>Other Plan Variables</b>	
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
<b>Drug utilization characteristics</b>	
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%
<b>Demographic characteristics</b>	
Age 65 to 74	47.4%
Original entitlement, other than age	6.5%
Female	63.1%
White	94.8%
Urban	48.3%
<b>State laws, for state of residence</b>	
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
<b>Generic Copays (Compared to \$0 copay)</b>		
\$1-4		
\$4-6		
>\$6		
<b>Brand Copays (Effect of additional \$10)</b>		
Lipitor		
Crestor		
Vytorin		
Other Brands		
<b>Utilization Management (Requirement for any brand in class)</b>		
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)
<b>Generics</b>		
Sertraline	22.7%	\$13.35
Citalopram	16.4%	\$10.33
Paroxetine	13.4%	\$20.00
Fluoxetine	12.5%	\$8.00
<b>Common Brands (all on-patent)</b>		
Lexapro	17.3%	\$83.16
Cymbalta	7.5%	\$118.33
Effexor	7.1%	\$120.09
<b>Other Brands (including off-patent)</b>		
All other brands	1.3%	\$117.60

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

# Comparing Antidepressants to Statins

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- **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

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- **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

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- **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

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- **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

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- **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

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- **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

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- **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

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- **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?**

- **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:

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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:

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

- A. 32%
- B. 54%
- C. 69%
- D. 88%