2010 Part D Symposium

Benefit Designs and Formularies, 2006 – 2010

Jack Hoadley, Georgetown University
Elizabeth Hargrave, NORC
Katie Merrell, Social & Scientific Systems

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

Credits

- Primary research support from MedPAC
- Additional research support from Kaiser Family Foundation
- Based on CMS landscape, formulary, and enrollment files

Analytical Notes

- Separate analysis for plan types
  - Standalone drug plans (PDPs)
  - Medicare Advantage MA-PDs (without SNPs)
  - Special needs plans (SNPs)
- Exclusions
  - Plans in territories
  - Employer-only plans
  - Demos, cost plans, other non-standard plans
- 2010 analysis:
  - Some exhibits use 2009 enrollment data
  - Some exclude plans suspended at time files were made available (primarily WellCare plans)

Goals

- Use of formularies, 2006-2010
  - Listing of drugs on formularies
  - Tiers and tier structures
  - Utilization management
- Variations
  - Across plans
  - Across drugs, drug classes

Definitions Needed

- What is a drug?
- What is a tier?
- What is a utilization management feature?
- *Different definitions will lead to significant variations in results.*

Drugs on Formulary

What is a Drug?

- We define “drug” as a unique chemical entity
- Versus alternatives:
  - NDC code
  - Unique forms and strengths
  - Brand or generic versions of a chemical entity
- Each chemical entity includes:
  - All forms and strengths
  - All trade names by which drug is marketed

Creating a Universe of “Drugs” in 2010

- Start from the 4,825 reference NDCs
- “Related SCDC” in the RxNorm system
  - Stripped of dosage information
- Compared result to prior-year universe
  - Prior years based on augmented USP list
  - Over 99% match rate
- Result: 1,107 “drugs” (chemical entities)

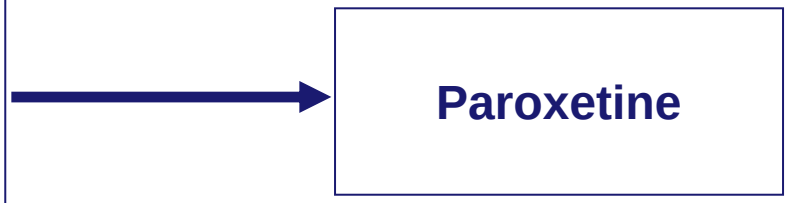
From 19 Reference NDCs to 1 “Drug”

Paroxetine (19 Reference NDCs)

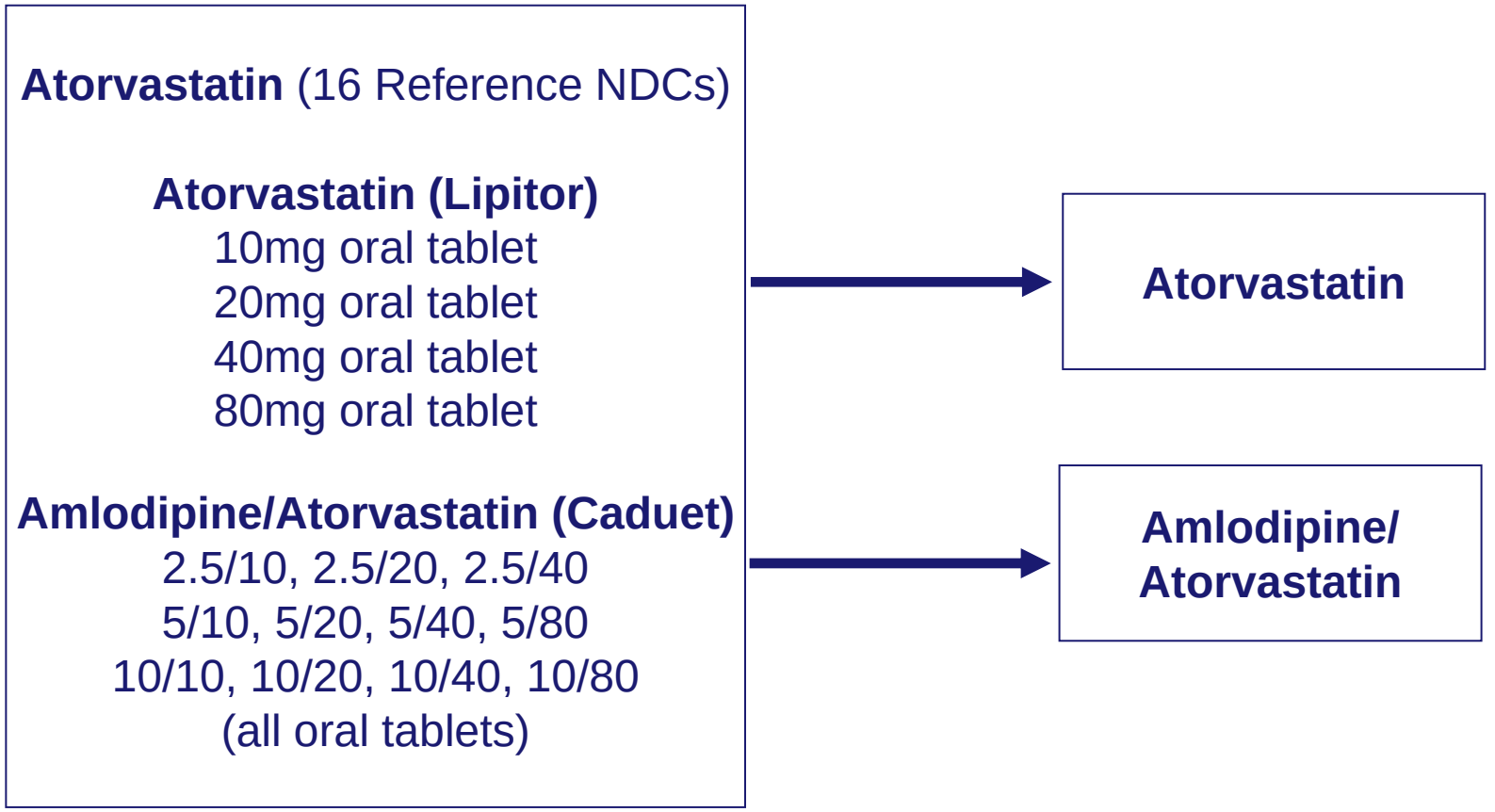
Generic Paroxetine (7 Ref. NDCs)
10mg, 20mg, 30mg, 40mg oral tablets
12.5mg, 25mg extended release tablets
2 mg/ml oral suspension

Brand Paxil (8 Ref. NDCs)
10mg, 20mg, 30mg, 40mg oral tablets
12.5mg, 25mg extended release tablets
37.5 extended release tablet
2 mg/ml oral suspension

Brand Pexeva (4 Ref. NDCs)
10mg, 20mg, 30mg, 40mg oral tablets



From 16 Reference NDCs to 2 “Drugs”

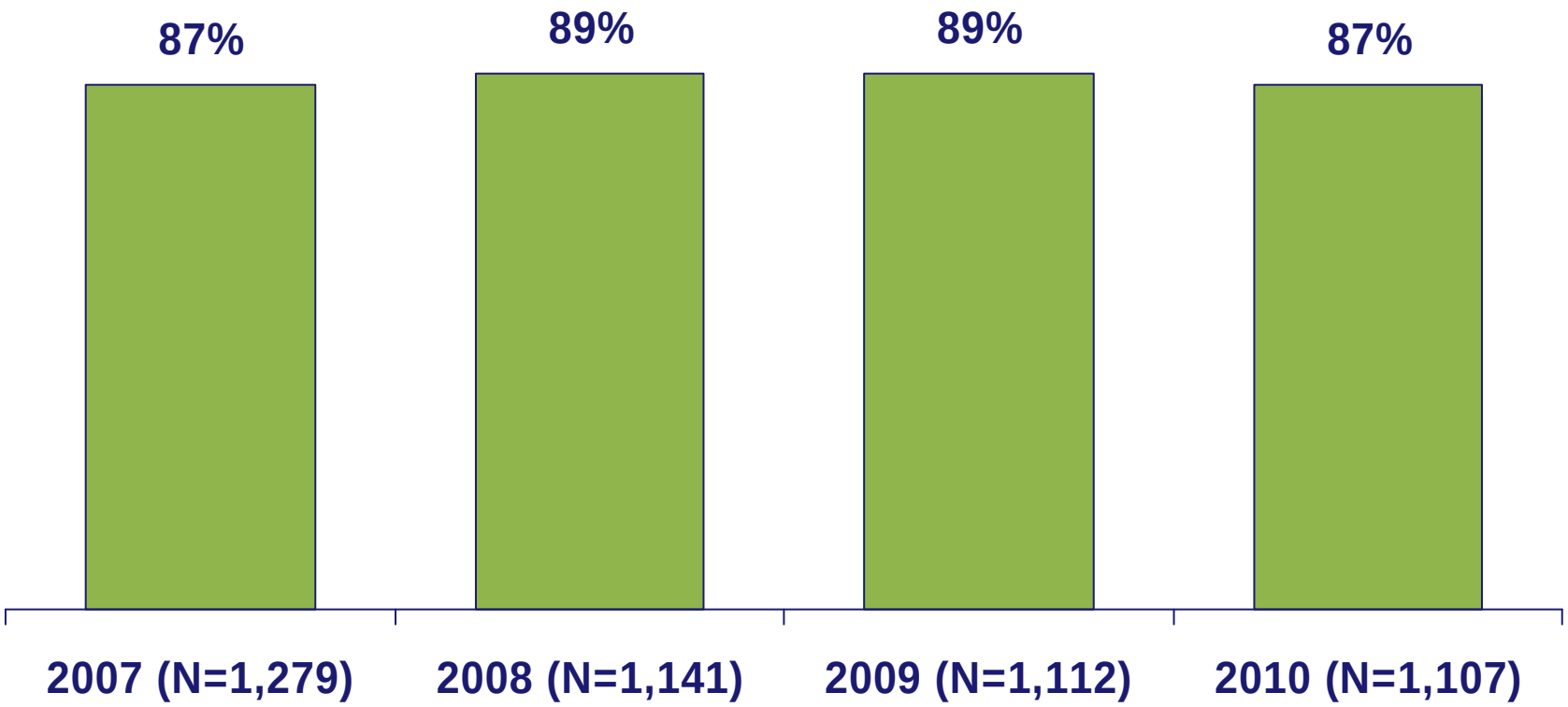


Defining Whether a Drug is on Formulary

- Plan formularies often do not cover all forms and strengths of a chemical entity
- We consider a drug listed on formulary when any component NDC is on formulary

Average Share of Drugs Listed Is Stable from Year to Year, PDPs, 2007-2010

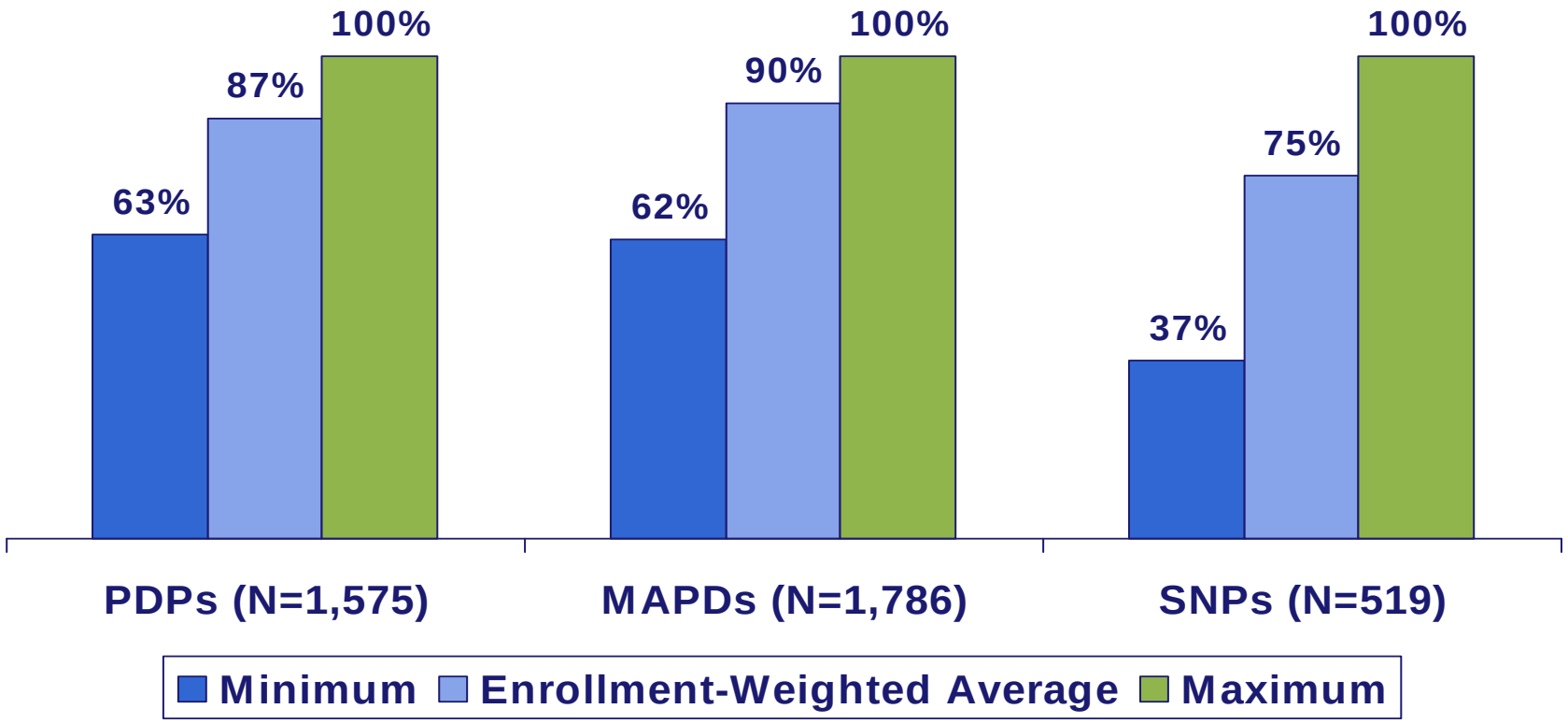
Share on Formulary of All Chemical Entities



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.

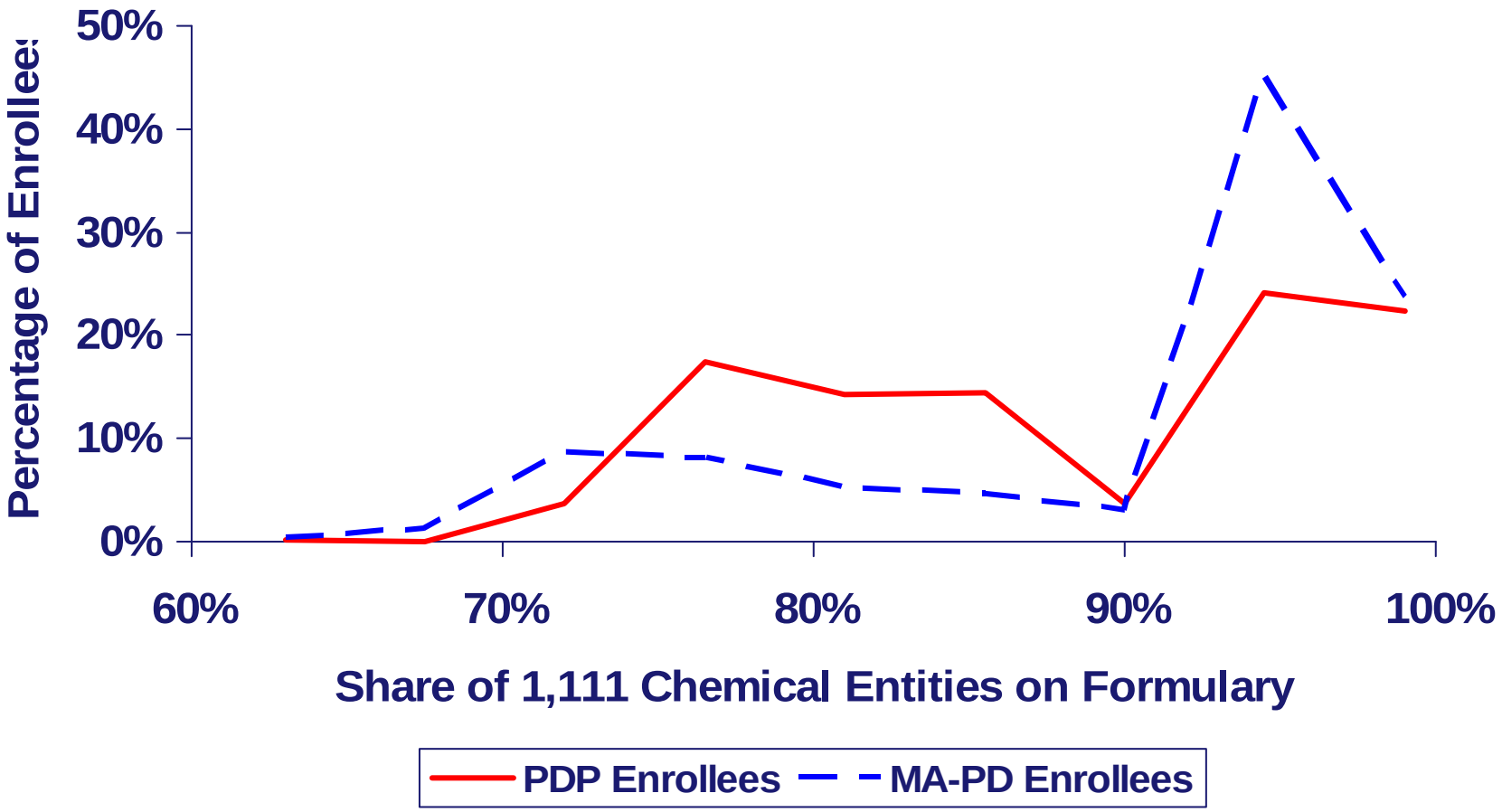
Similar Formularies for PDPs & MAPDs, But Smaller Formularies for SNPs, 2010

Share on Formulary of All 1,107 Chemical Entities



NOTE: Calculations are shares of all chemical entities on the CMS reference file, weighted by enrollment. Ns are numbers of plans.

Despite Similar Averages, MA Beneficiaries More Likely in Plans with at Least 90% of Drugs on Formulary, 2010



NOTE: Calculations are distributions of 2009 enrollments, based on CMS plan crosswalks.

Plans' Use of Cost-Sharing Tiers

Standardizing Tier Structures

- MMA gives plans flexibility to create cost-sharing tiers within bounds of actuarial equivalence
- Analytical goal: Identify standard tier designs where possible
- Principle: Where plans label additional tiers, but have the same cost sharing, we combined them

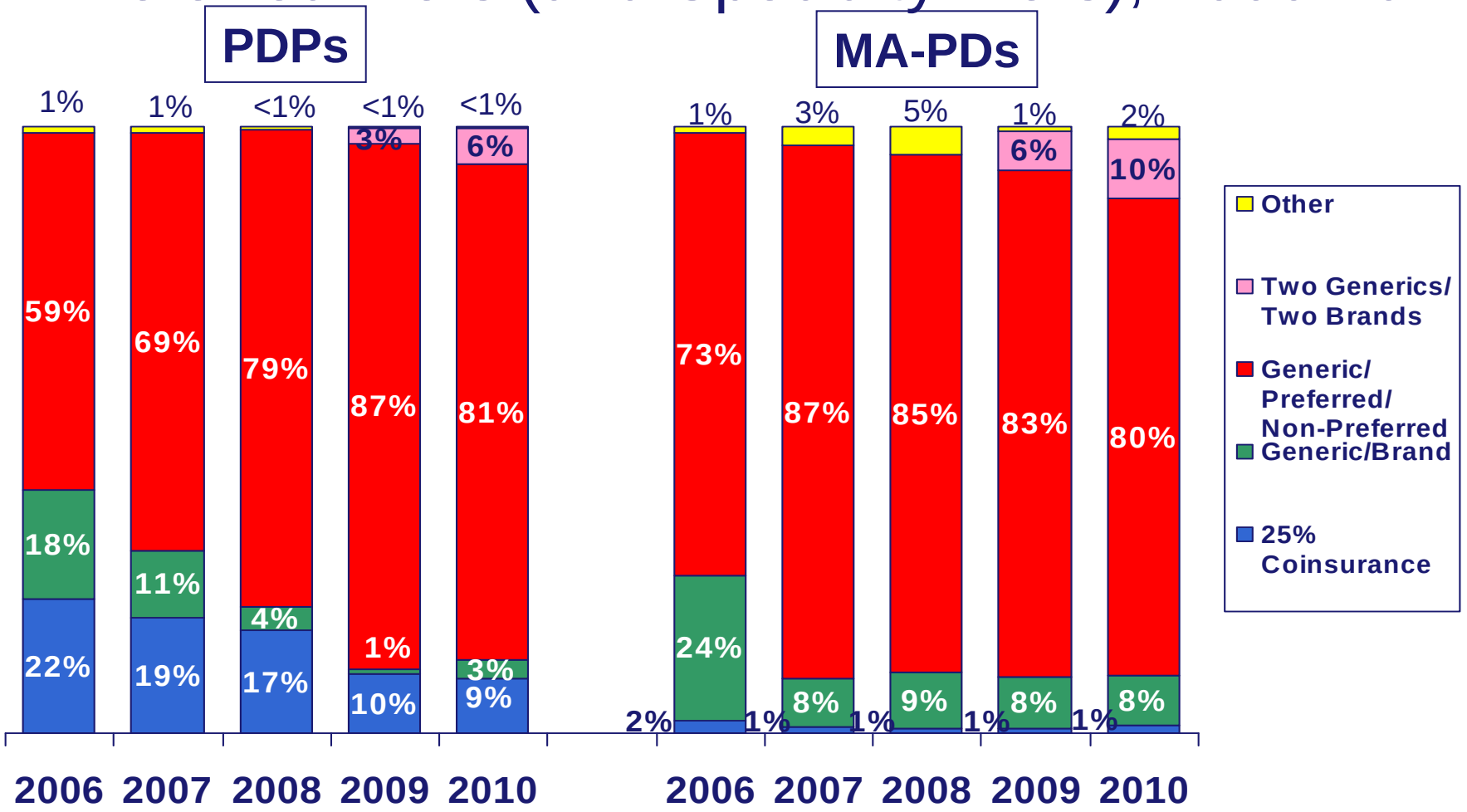
Example of One Plan's Tiers

Tiers Submitted to CMS	Analytical Tiers
1: Preferred Generics ($5)	**G**: Generics
2: Nonpreferred Generics ($5)	
3: Preferred Brands ($27)	**PB**: Preferred Brands
4: Nonpreferred Brands ($65)	**NPB**: Nonpreferred Brands
5: Specialty Drugs (25%)	**S**: Specialty Drugs
6: Injectible Drugs (25%)	

PDPs and MA-PDs Use a Variety of Cost Sharing Designs

- *Statutory benefit design now used by plans with less than 10% of all enrollees*
- *Most common tier structure (about 80% of enrollees)*
  - Single tier for generic drugs
  - Two tiers for brand drugs (Preferred, Non-Preferred)
    - May include some higher-priced generic drugs
  - Specialty tier for expensive drugs (e.g., biologicals)
- *Most common variations*
  - Single brand tier
  - Second generic tier (Value, Non-Preferred)
  - Third brand tier for (Value Brands)
  - Non-specialty injectible tier

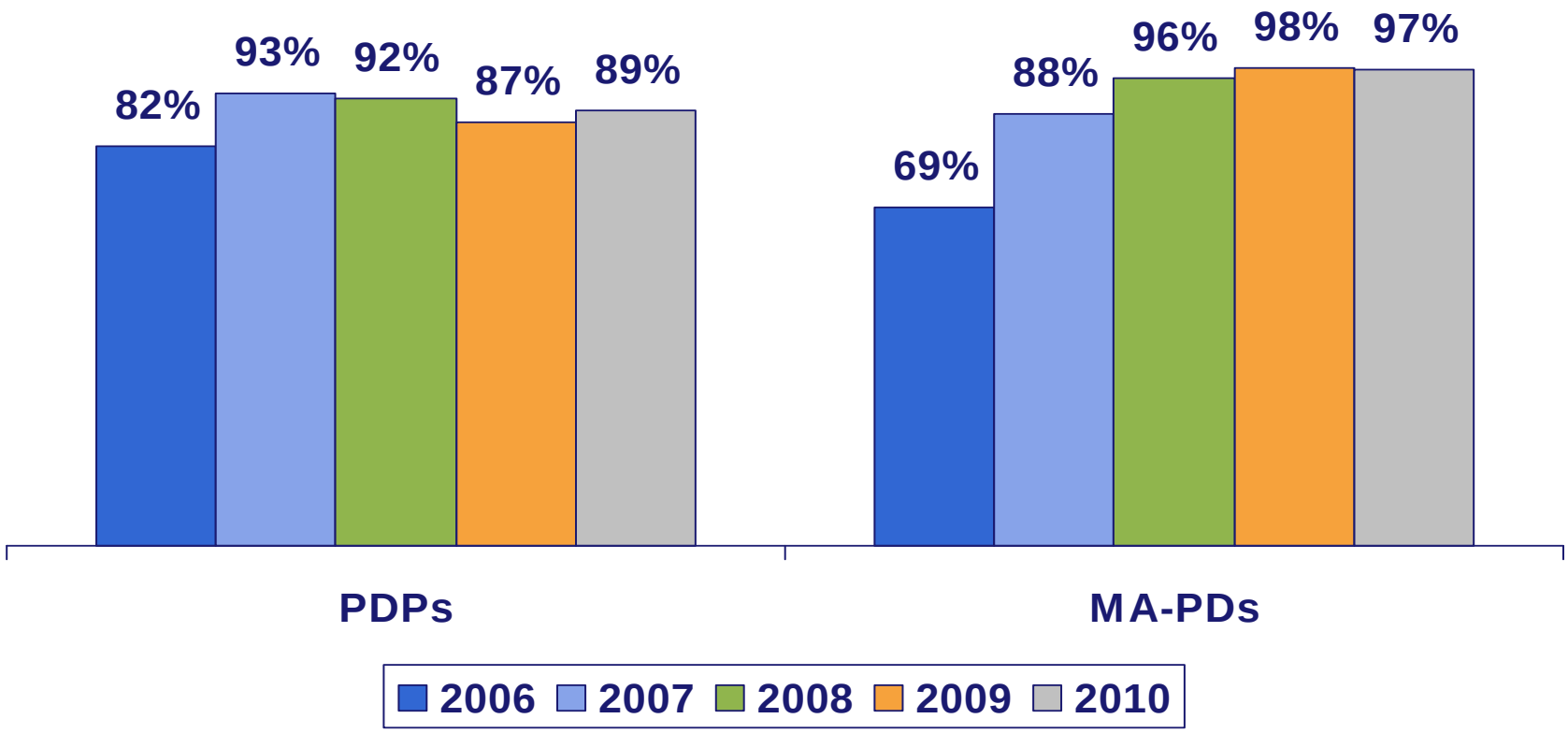
Plans Most Often Use Generic, Preferred, and Non-Preferred Tiers (and Specialty Tiers), 2006-10



NOTE: Most non-standard plans also use specialty tiers. Calculations are share of plans, weighted by enrollment.

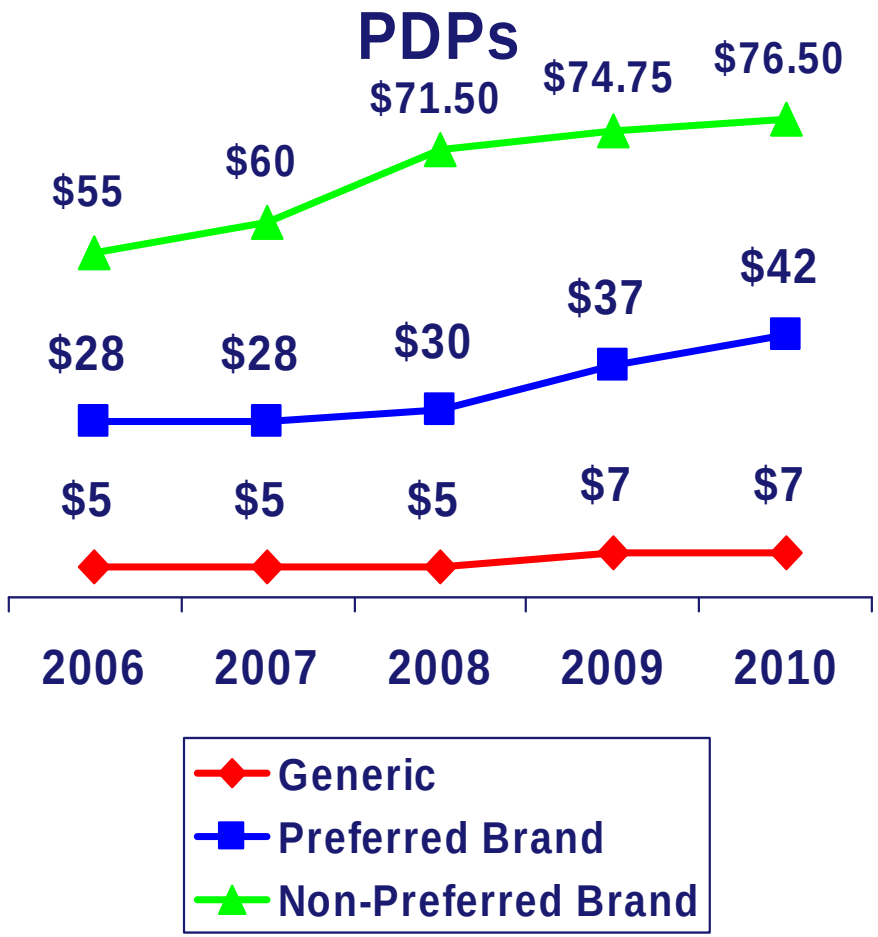
Most Plans Use Specialty Tiers for Some Expensive Drugs, 2006-2010

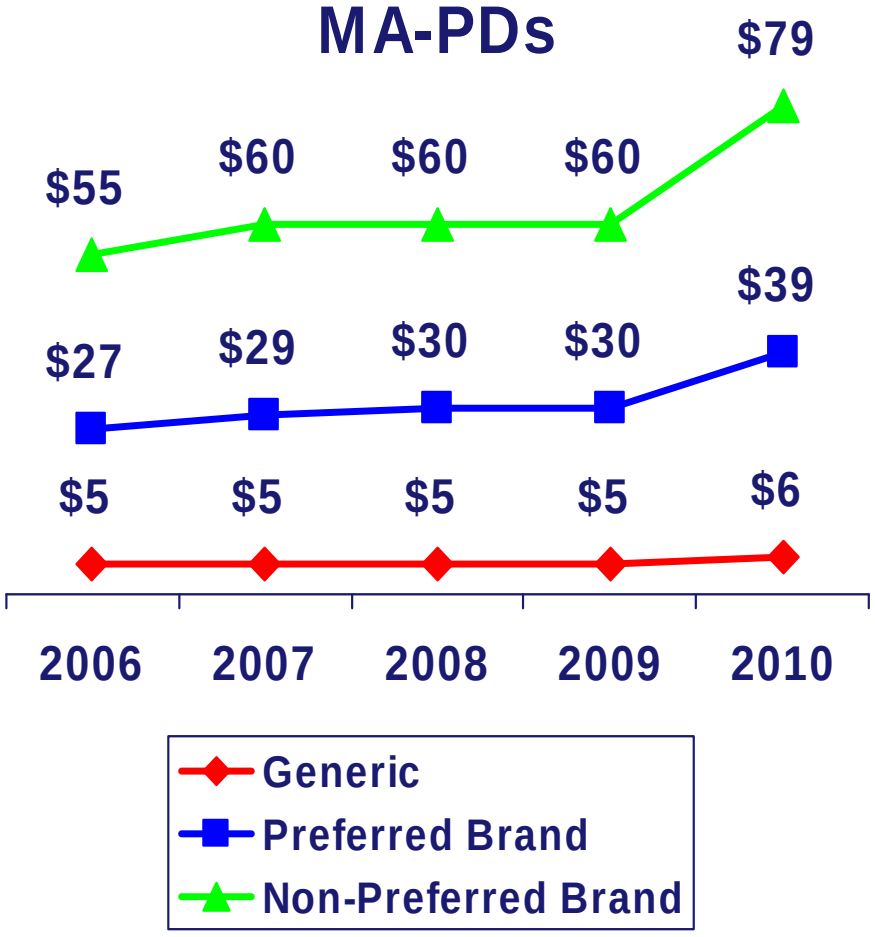
Share of Plans with Non-Standard Tier Structures



NOTE: Calculations are share of all plans, weighted by enrollment.

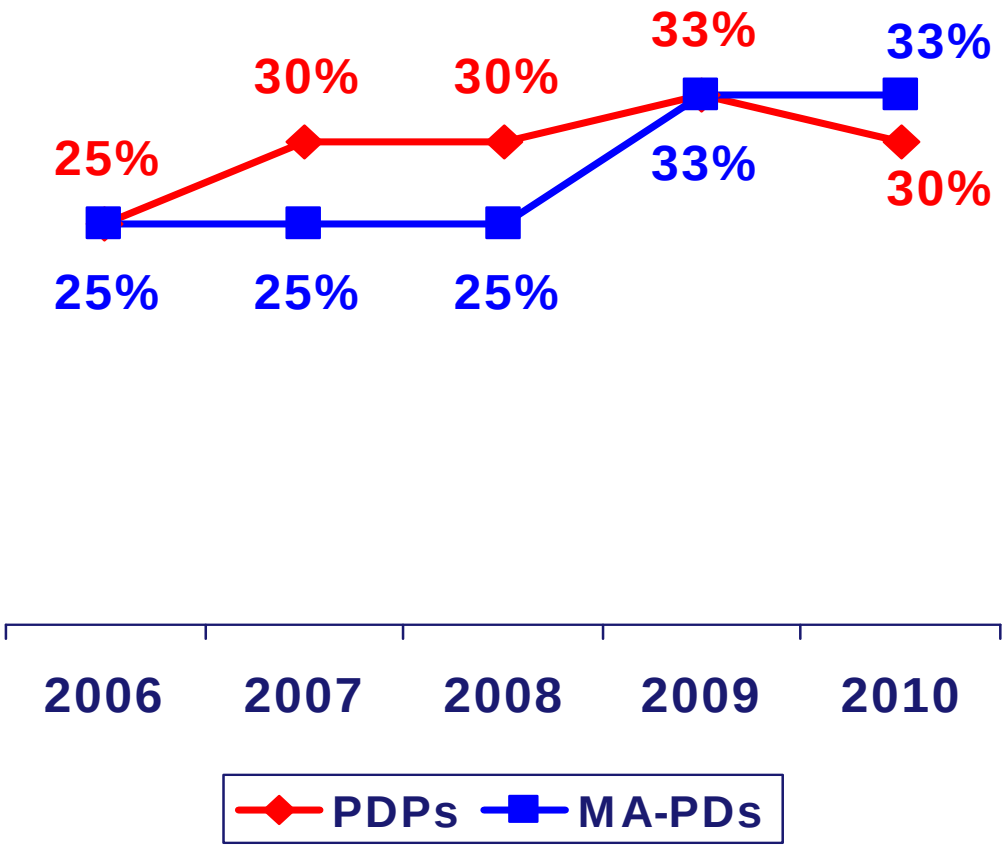
Median Cost Sharing for a Month's Supply of a Drug Has Risen Over Time, 2006-2010





NOTE: Calculations are weighted by enrollments; exclude generic/brand plans, plans with coinsurance.

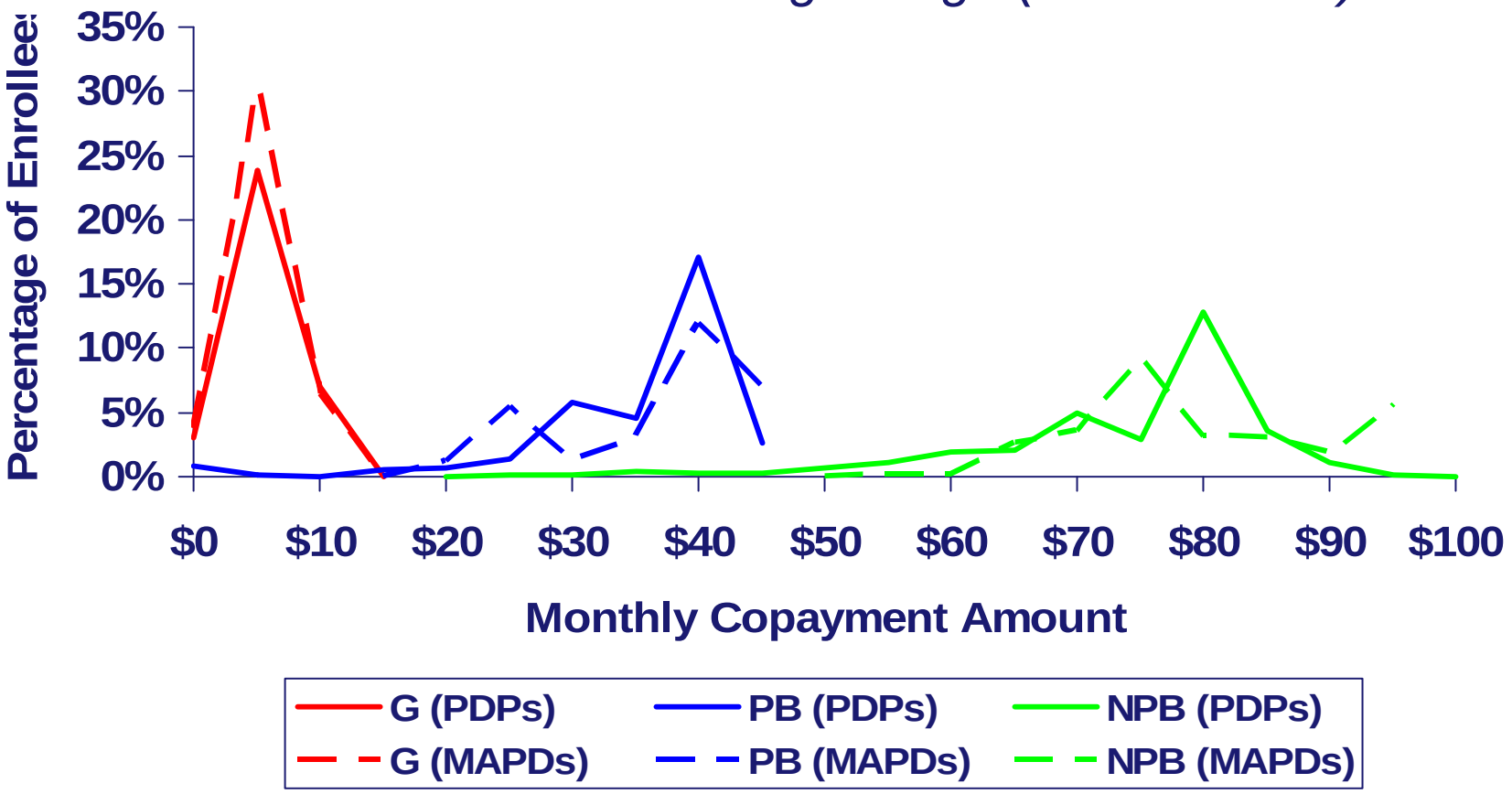
Median Cost Sharing for Specialty Tier, 2006-2010



NOTE: Calculations are weighted by enrollments.

Copayment Amounts Vary Across Plans and Plan Types, 2010

Most Common Cost Sharing Design (G/PB/NPB/S)



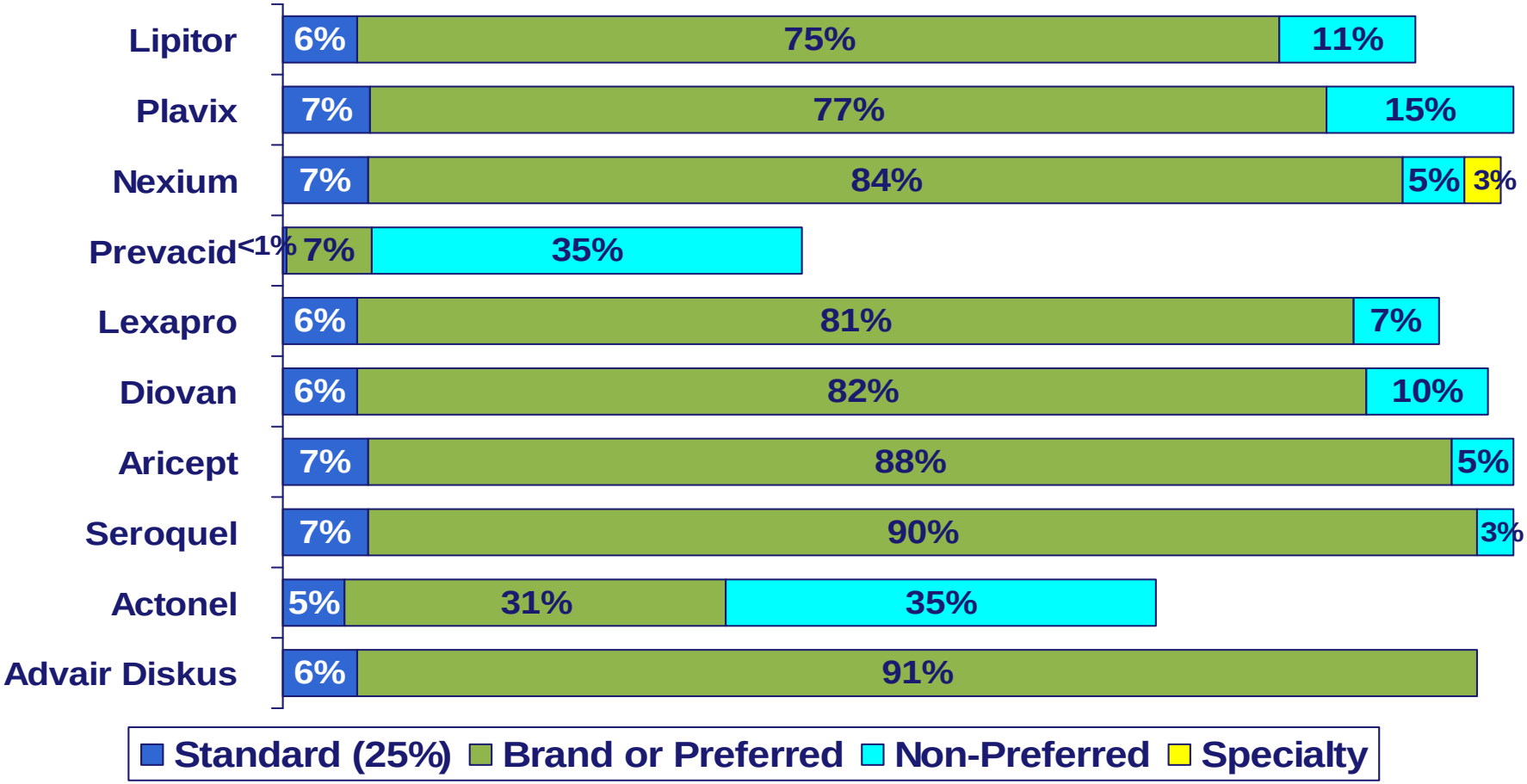
NOTE: Calculations are distributions of 2009 enrollments, based on CMS plan crosswalks.

Placement of Drugs on Cost-Sharing Tiers

Assigning Tiers to Drugs

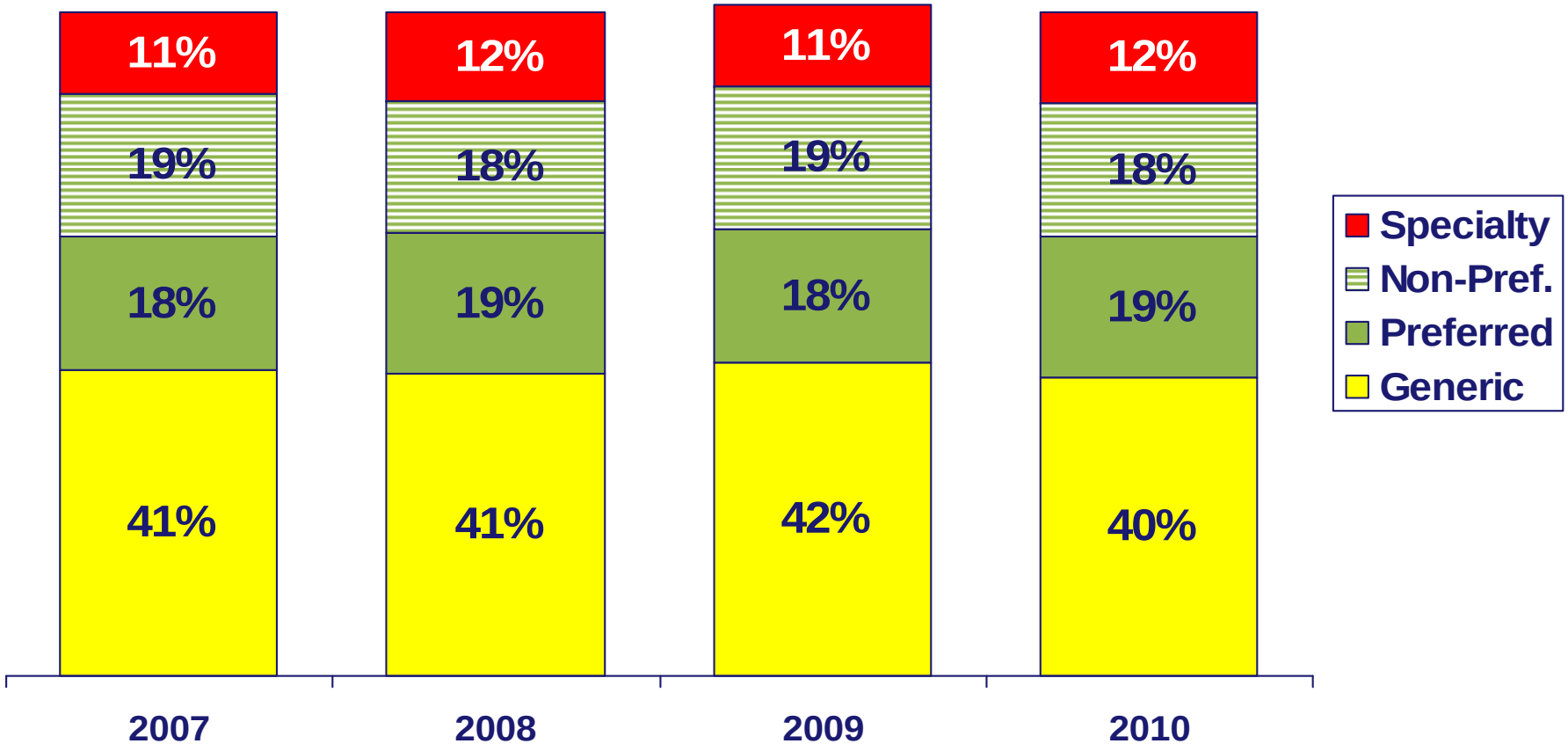
- Plan formularies may assign different NDCs to different tiers
  - Generic paroxetine to G tier
  - Brand Paxil to NPB tier
- We assign drug to the “lowest” tier that occurs
  - In order: G / PB / NPB / S

Top Brand Drugs Vary in Formulary and Tier Status, PDPs, 2010



NOTE: Calculations are share of all PDPs, weighted by 2009 enrollments.

Distribution of Drugs by Tier in PDPs with Most Common Tier Structure, 2007-2010



NOTE: Some plans do not use specialty tiers. Calculations are share of chemical entities, weighted by enrollments.

Utilization Management

Assigning Utilization Management

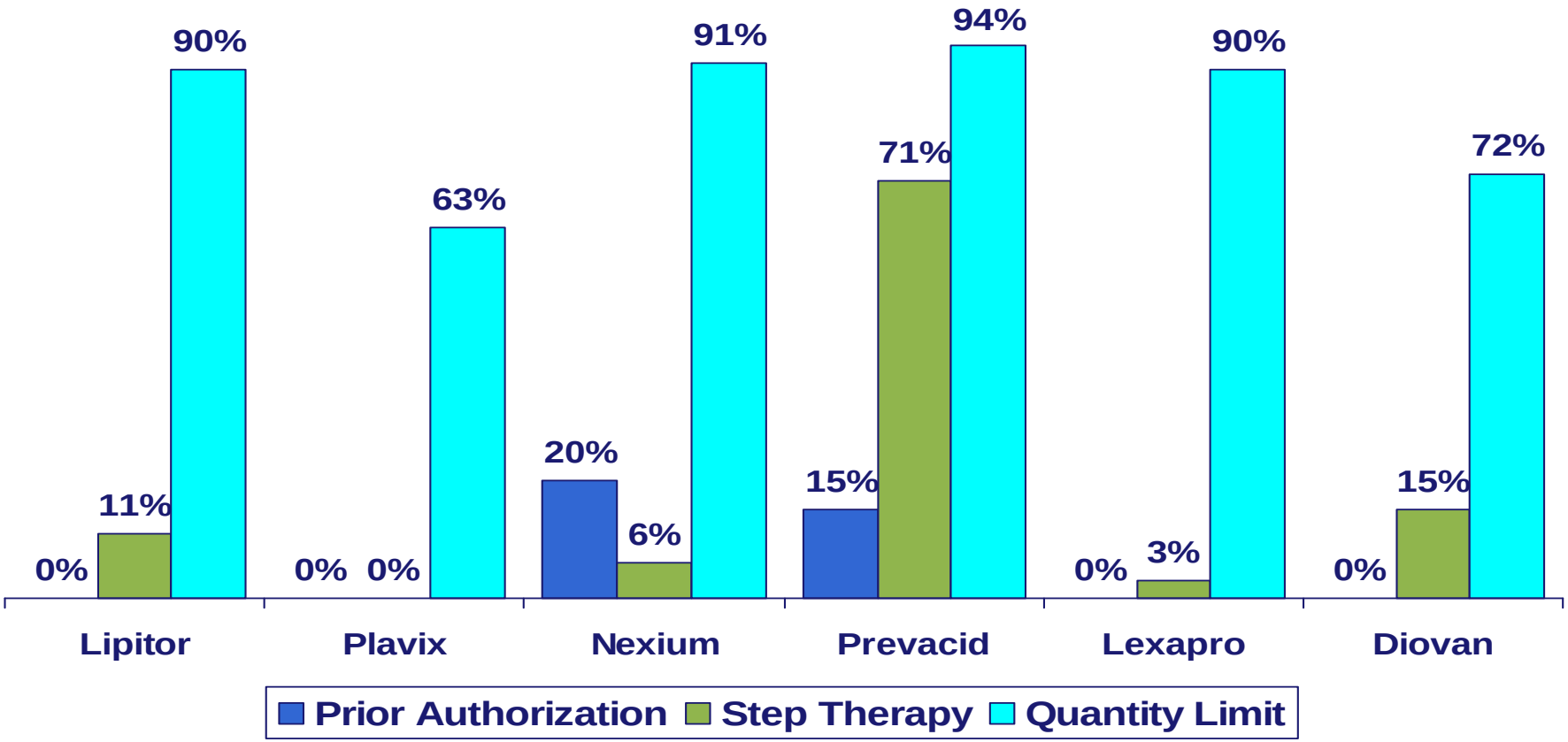
- Utilization management flags
  - Prior authorization (PA)
  - Step therapy (ST)
  - Quantity limits (QL)
- Plan formularies may vary UM use for different forms and strengths of a drug
- We assign a UM flag to a drug if the flag is used for any component NDC
  - Currently testing alternative definitions

Most Plans Use All Types of Utilization Management

	Ever Use PA?	Ever Use ST?	Ever Use QL?
PDPs	100%	94%	100%
MA-PDs	100%	88%	98%
SNPs	100%	91%	99%

NOTE: Calculations are share of all PDPs, not weighted.

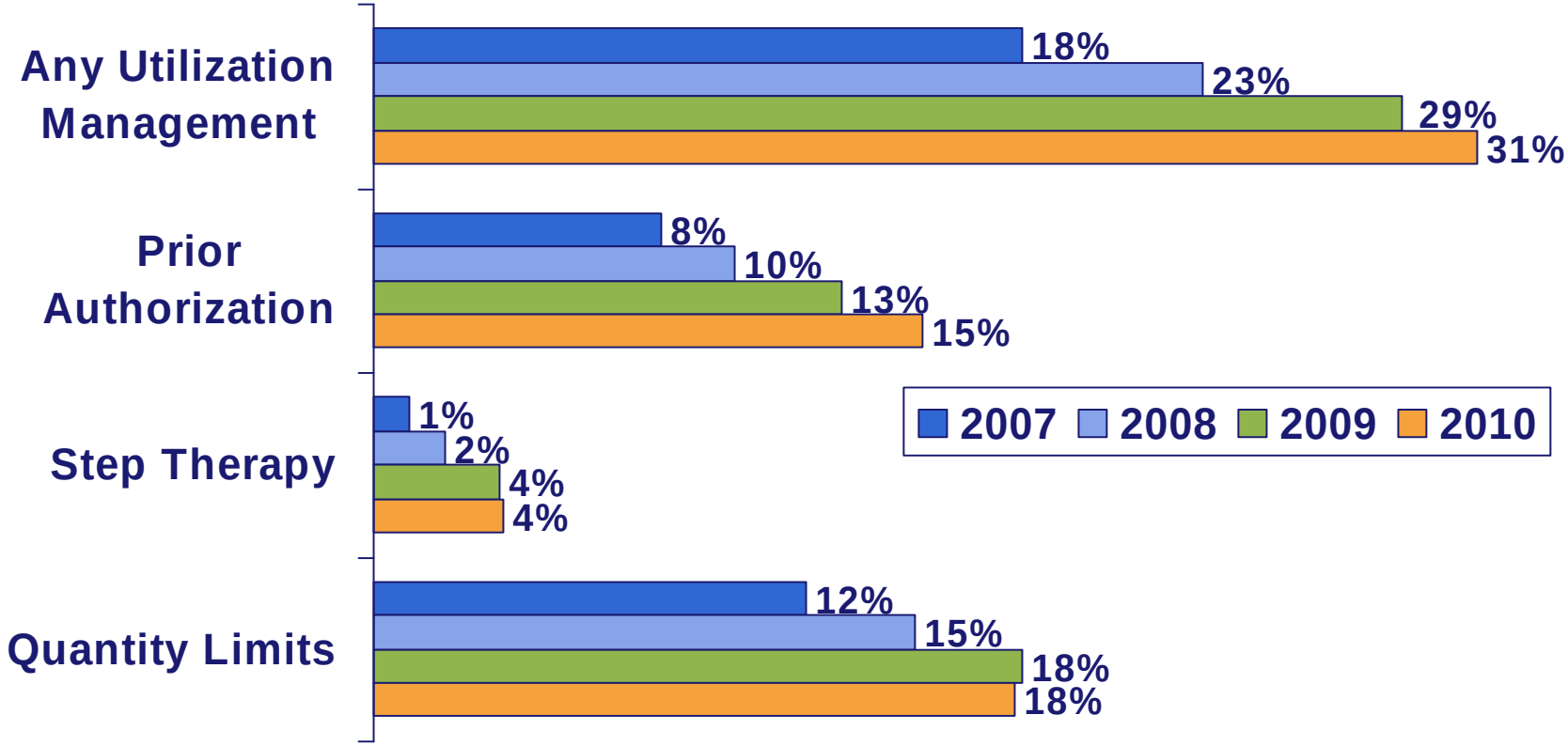
Selected Top Brands Vary in Utilization Management Restrictions, PDPs, 2010



NOTE: Calculations are share of all PDPs, weighted by 2009 enrollments.

Gradual Increases in Share of Drugs with Utilization Management, PDPs, 2007-2010

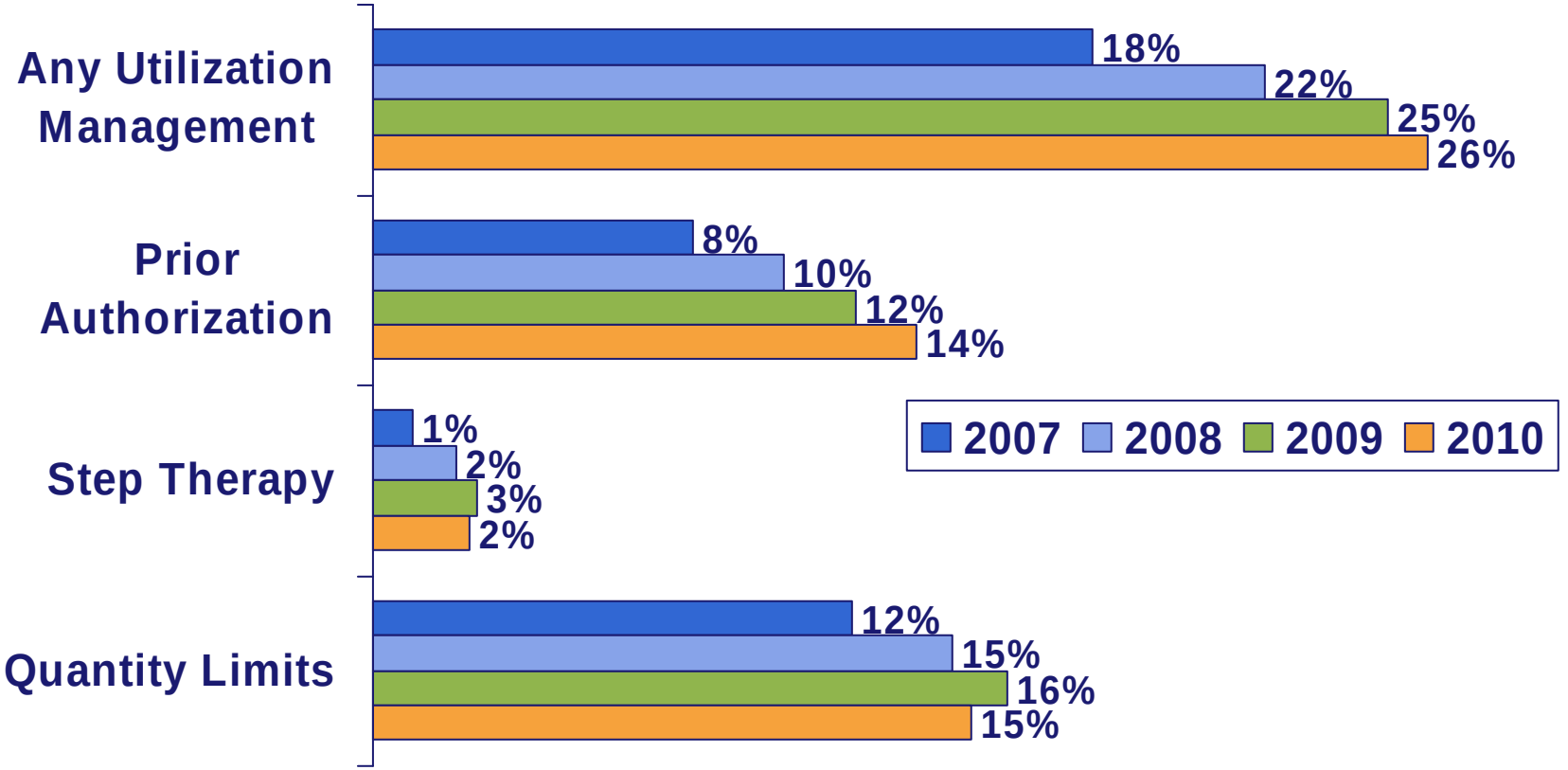
Average Share of Listed Drugs



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

Gradual Increases in Share of Drugs with Utilization Management, MA-PDs, 2007-2010

Average Share of Listed Drugs



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

Measuring Formularies: Total Drugs Versus Total Unrestricted Drugs

Formulary Listing ≠ Coverage

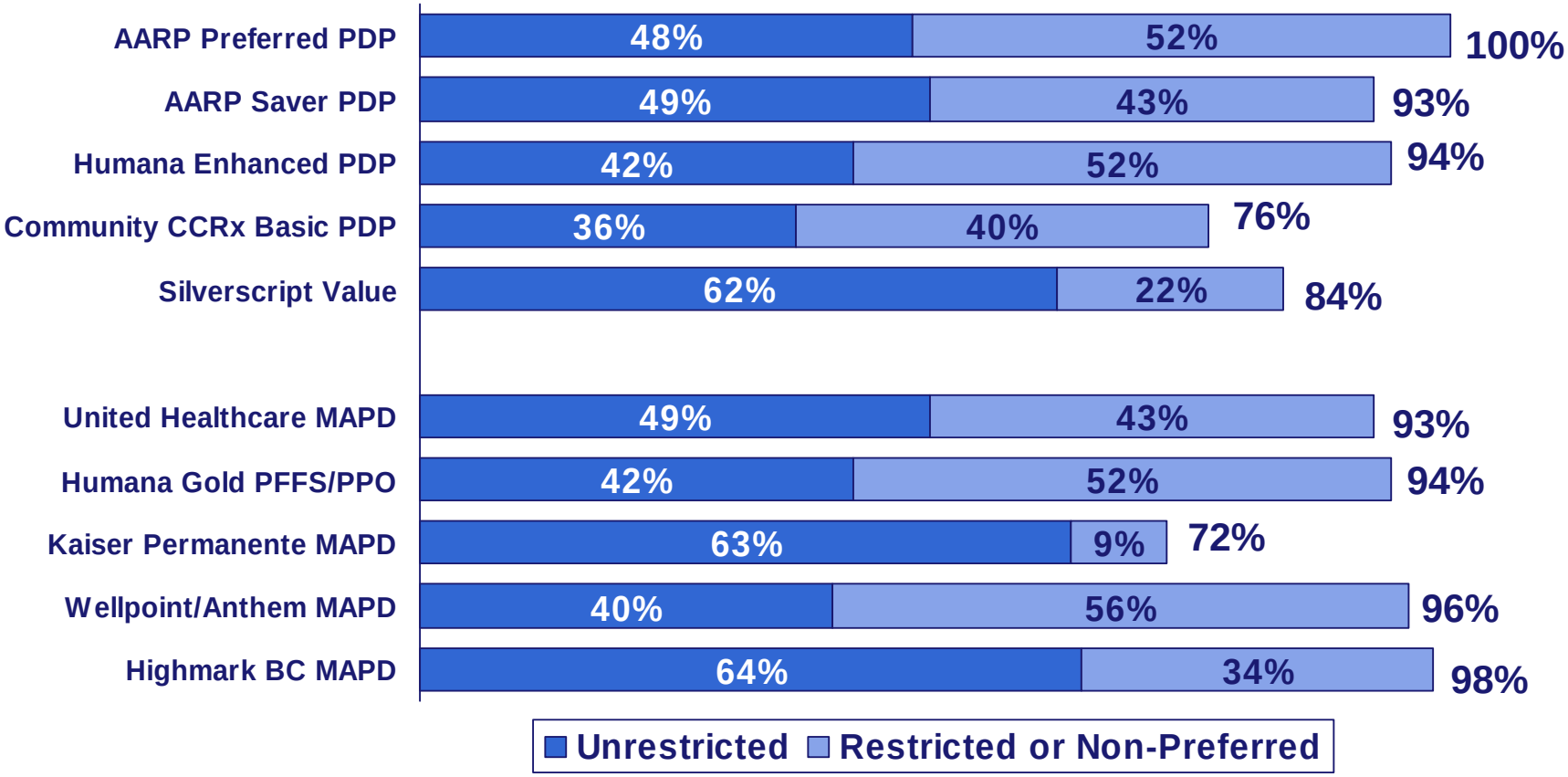
- When a drug is on formulary, coverage may be restricted:
  - Utilization management restrictions
  - High cost-sharing tier
- When a drug is off formulary, coverage may be possible:
  - Formulary exception
  - Temporary fill in transition coverage

Alternate Formulary Measures

- Total drugs on formulary
  - Without regard to tiers or UM restrictions
- Total unrestricted drugs
  - Drug on formulary
  - No UM restrictions
  - Favored tier
    - Any generic tier
    - Preferred brand tier or single brand tier
    - Standard 25 percent coinsurance

Formulary Listings Vary in 2010 for Plans with Highest Enrollment

Share of Chemical Entities

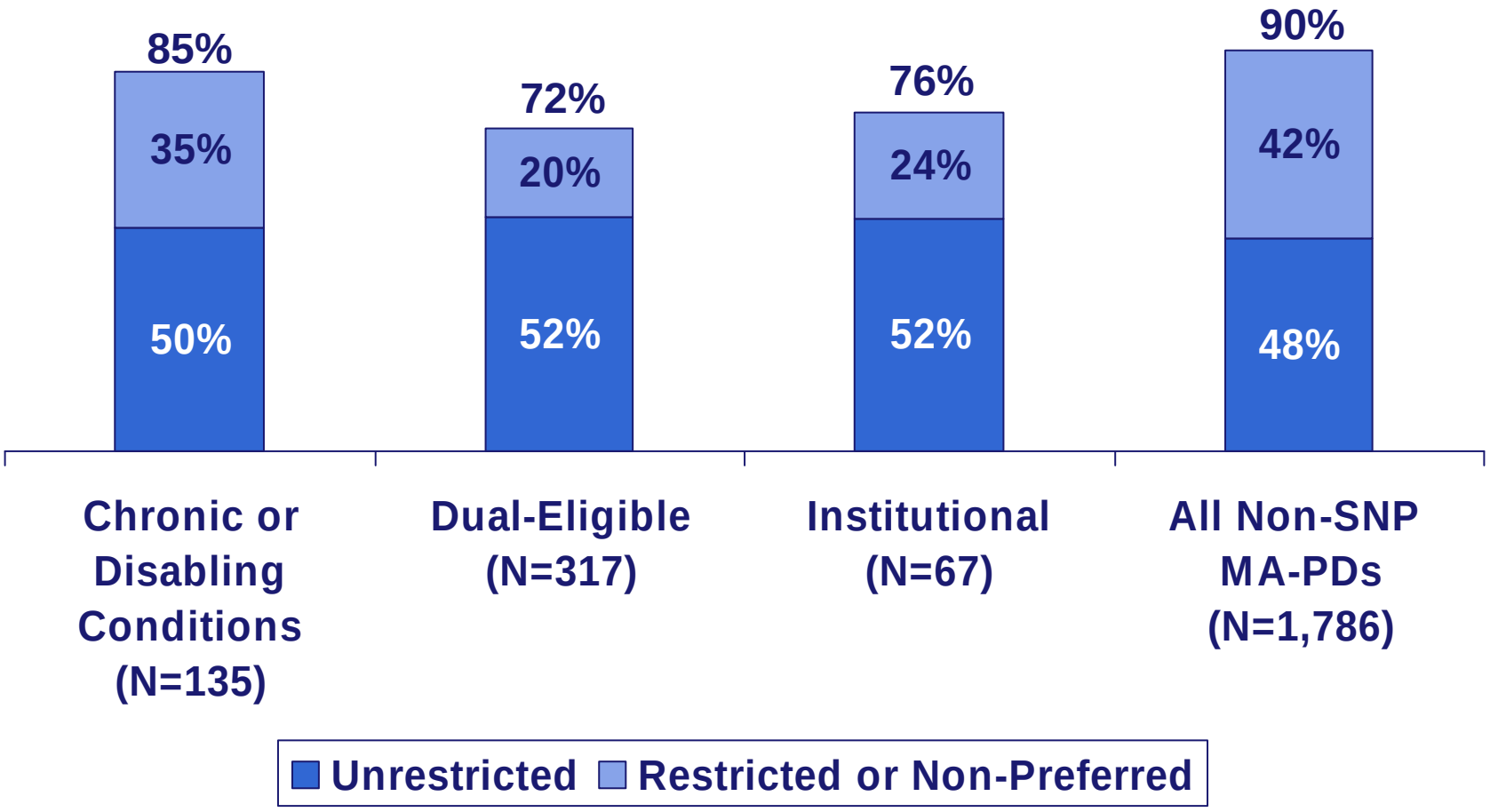


NOTE: Calculations are share of chemical entities. Totals may not add due to rounding.

Formulary Size Varies Based on Some Differences in Plan Types, 2010

- PDPs with enhanced benefits list *slightly fewer* drugs than basic-benefit PDPs
  - But may also offer some non-Part D drugs
- HMOs have modestly smaller formularies than PFFS plans or local or regional PPOs
- PDPs offered by national sponsors have modestly larger formularies than PDPs of sponsors present in one or a few regions

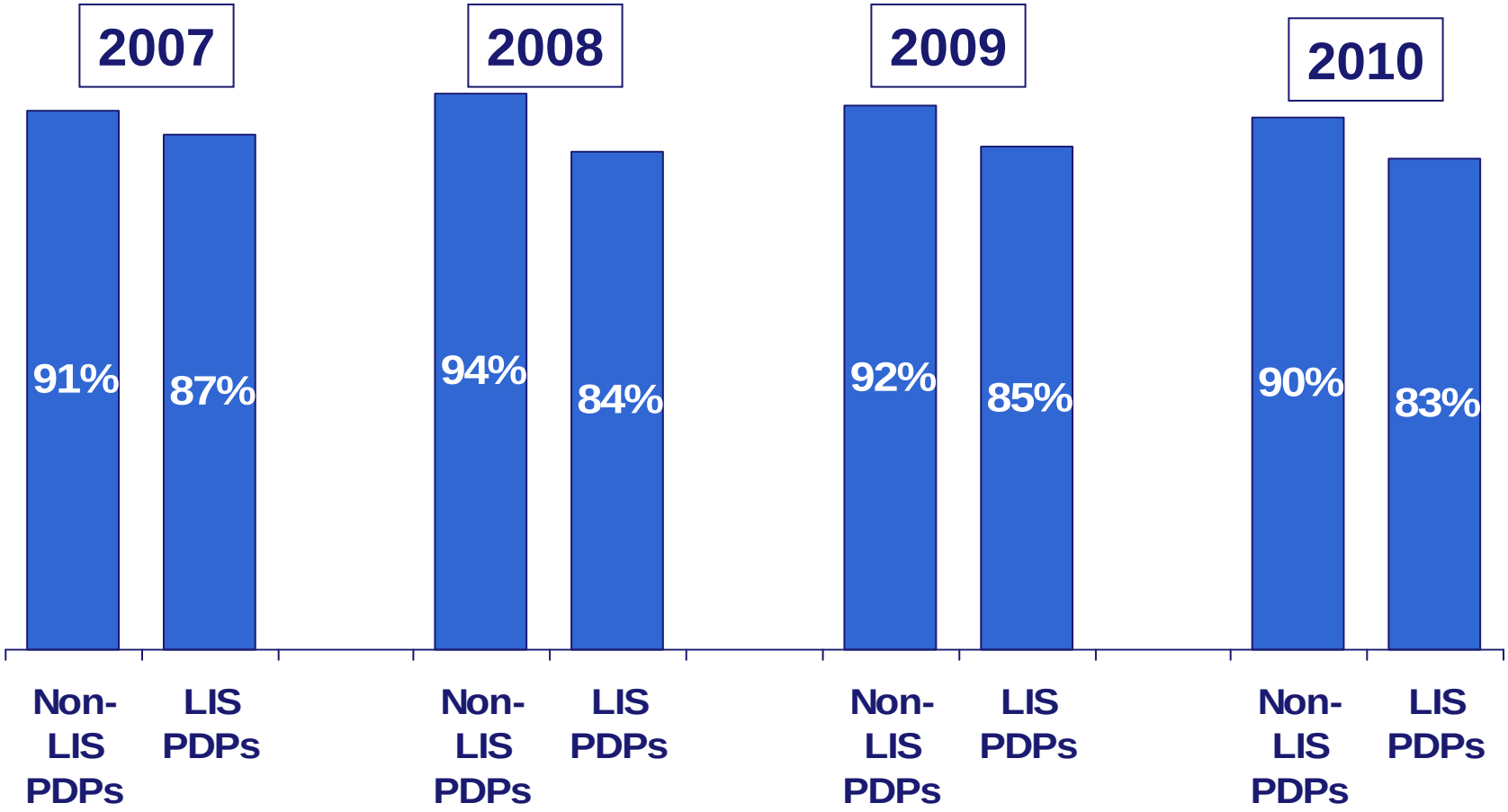
All Types of SNPs List Fewer Drugs than Non-SNP MA-PDs, 2010



NOTE: Calculations are share of chemical entities, weighted by enrollment. Ns are numbers of plans.

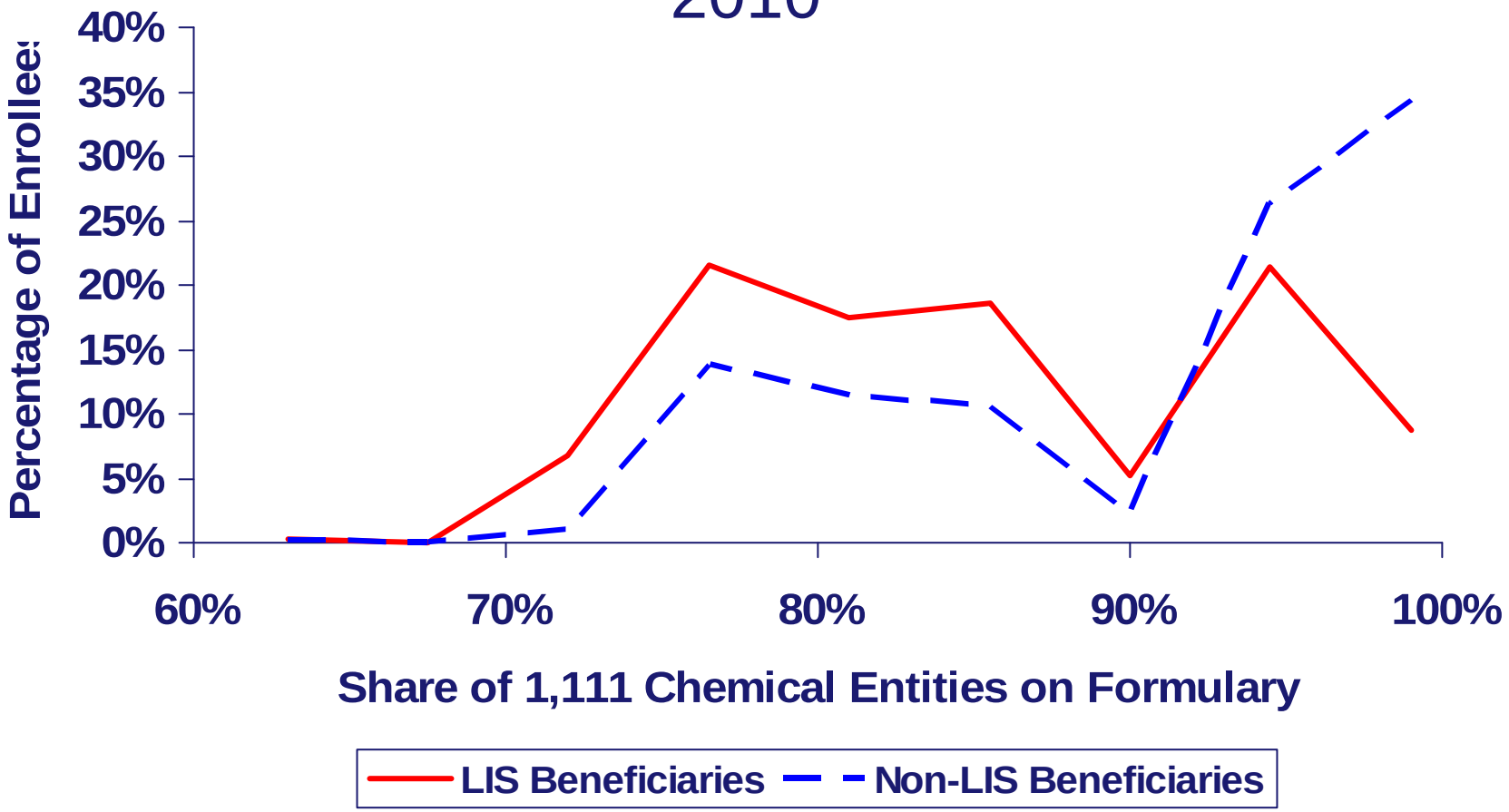
Are Formularies Different for LIS Benchmark Plans?

LIS Benchmark PDPs Tend to Have Modestly Smaller Formularies, 2007-2010



NOTE: Excludes plans that qualified to keep LIS enrollees based on the waiver for 2007 and 2008. Calculations are share of chemical entities, weighted by enrollments.

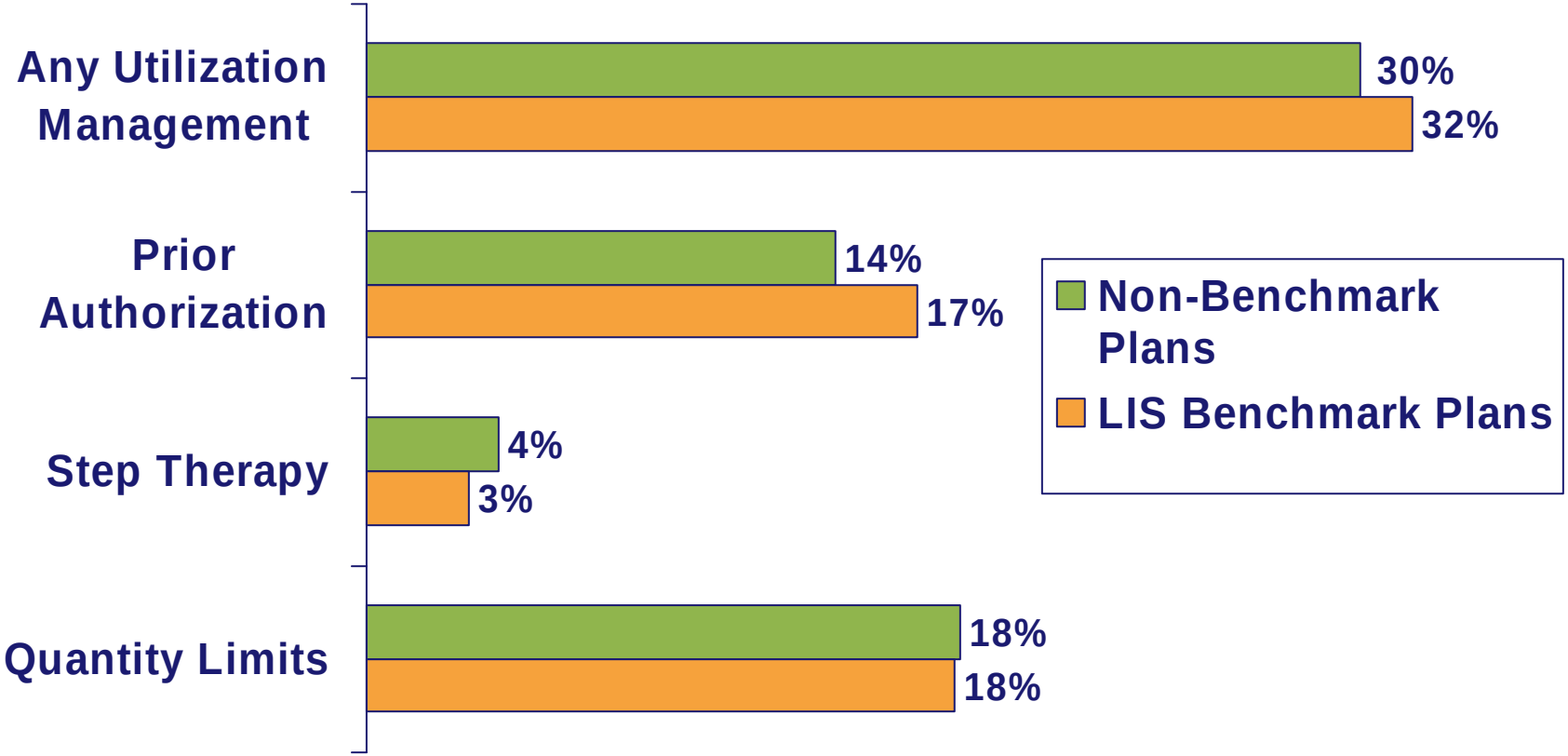
LIS Beneficiaries, Whether or Not in Benchmark Plans, Tend to Be in PDPs with Fewer Drugs on Formulary, 2010



NOTE: Calculations are distributions of 2009 enrollments, based on CMS plan crosswalks.

Enrollees in LIS PDPs About as Likely to Face Utilization Management

Average Share of Listed Drugs, 2010



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

Formulary Differences by Drug Classes

Tier Assignment Varies by Drug Class, PDPs, 2010

Drug Class *(Protected - Italics)*	**Off**	**G/PG**	**B/PB**	**NPB**	**S**
Antineoplastics	1%	13%	22%	14%	42%
Atypical Antipsychotics	0%	21%	39%	32%	0%
Reuptake Inhibitors (Antidepressants)	1%	66%	20%	4%	0%
Antidiabetic Agents	9%	43%	25%	15%	0%
ACE Inhibitors (Hypertension)	7%	81%	0%	5%	0%
ARBs (Hypertension)	33%	0%	29%	35%	0%
Cholesterol Drugs	7%	54%	24%	8%	0%
H2 Blockers (Gastrointestinal)	6%	86%	0%	1%	0%
Proton Pump Inhibitors (Gastro)	30%	20%	27%	16%	2%

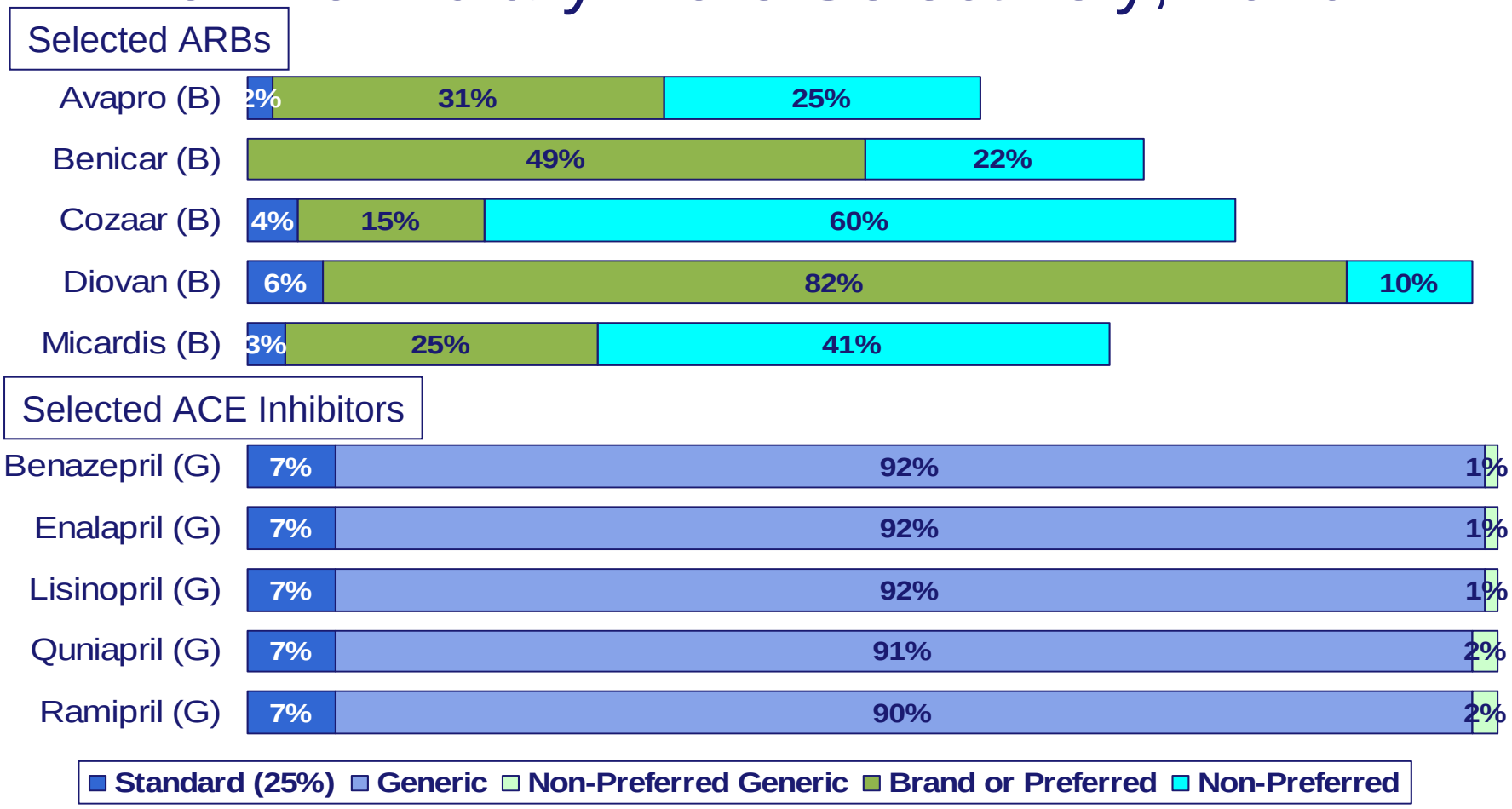
NOTE: Calculations are share of all PDPs, weighted by 2009 enrollment and averaged across drugs. Excludes standard 25% coinsurance, non-preferred generic tiers, non-standard tiers.

Utilization Management Varies by Drug Class, PDPs, 2010

Drug Class *(Protected in Italics)*	**PA**	**ST**	**QL**
Antineoplastics	39%	2%	19%
Atypical Antipsychotics	13%	31%	65%
Reuptake Inhibitors (Antidepressants)	2%	11%	72%
Antidiabetic Agents	7%	24%	27%
ACE Inhibitors (Hypertension)	0%	0%	10%
ARBs (Hypertension)	0%	38%	79%
Cholesterol Drugs	2%	9%	50%
H2 Blockers (Gastrointestinal)	2%	0%	0%
Proton Pump Inhibitors (Gastrointestinal)	10%	41%	88%

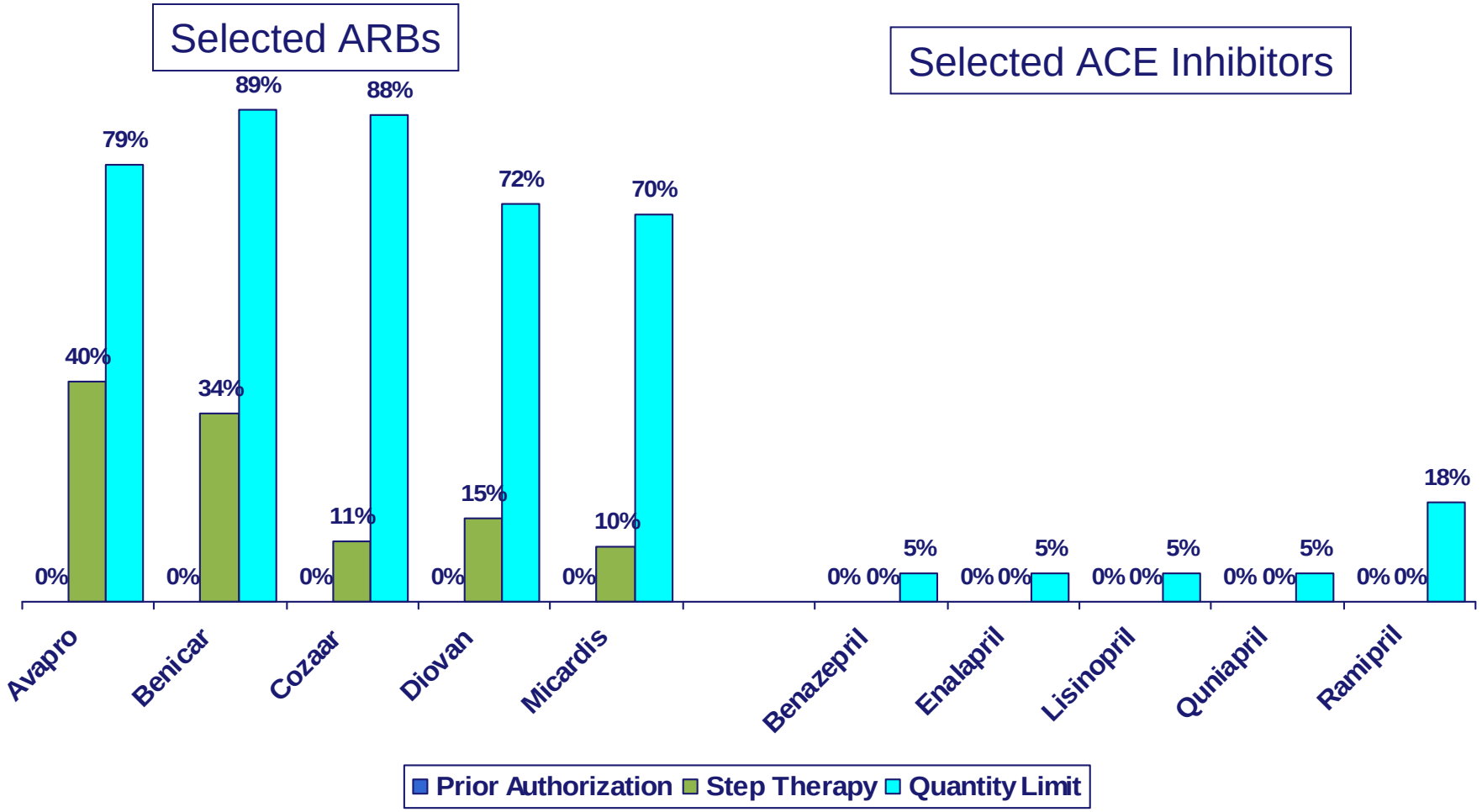
NOTE: In protected classes, UM restrictions are mostly not applicable to those currently taking a drug.
NOTE: Calculations are share of all PDPs, weighted by 2009 enrollment and averaged across drugs.

ACE Inhibitors Uniformly on Formulary, ARBs on Formulary More Selectively, 2010



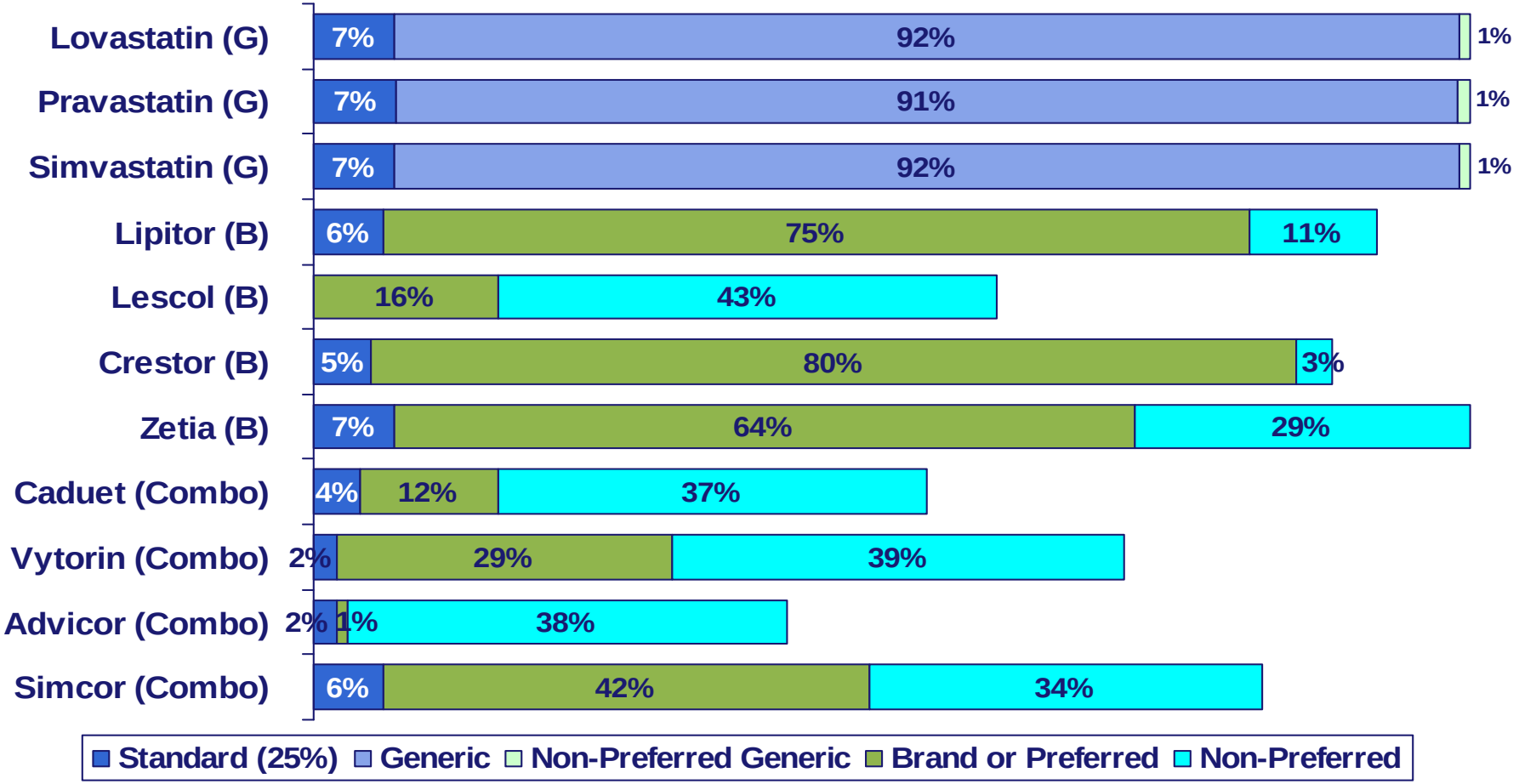
NOTE: Calculations are share of all PDPs, weighted by 2009 enrollments.

ARBs Much More Likely Than ACEs to Be Subject to UM Restrictions, 2010



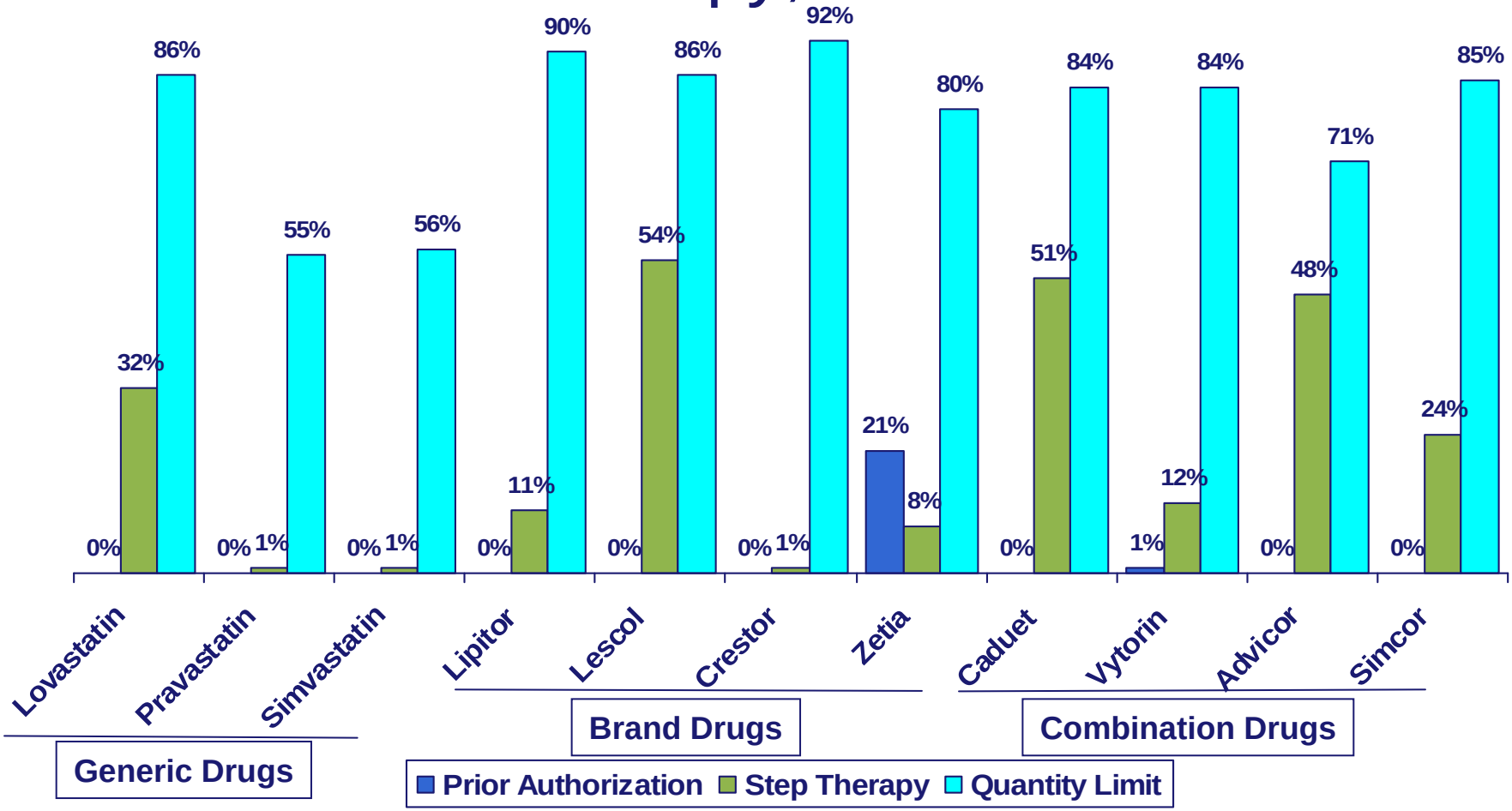
NOTE: Calculations are share of all PDPs listing drug on formulary, weighted by 2009 enrollments.

Cholesterol Drugs Vary in Tier and Formulary Status, PDPs, 2010



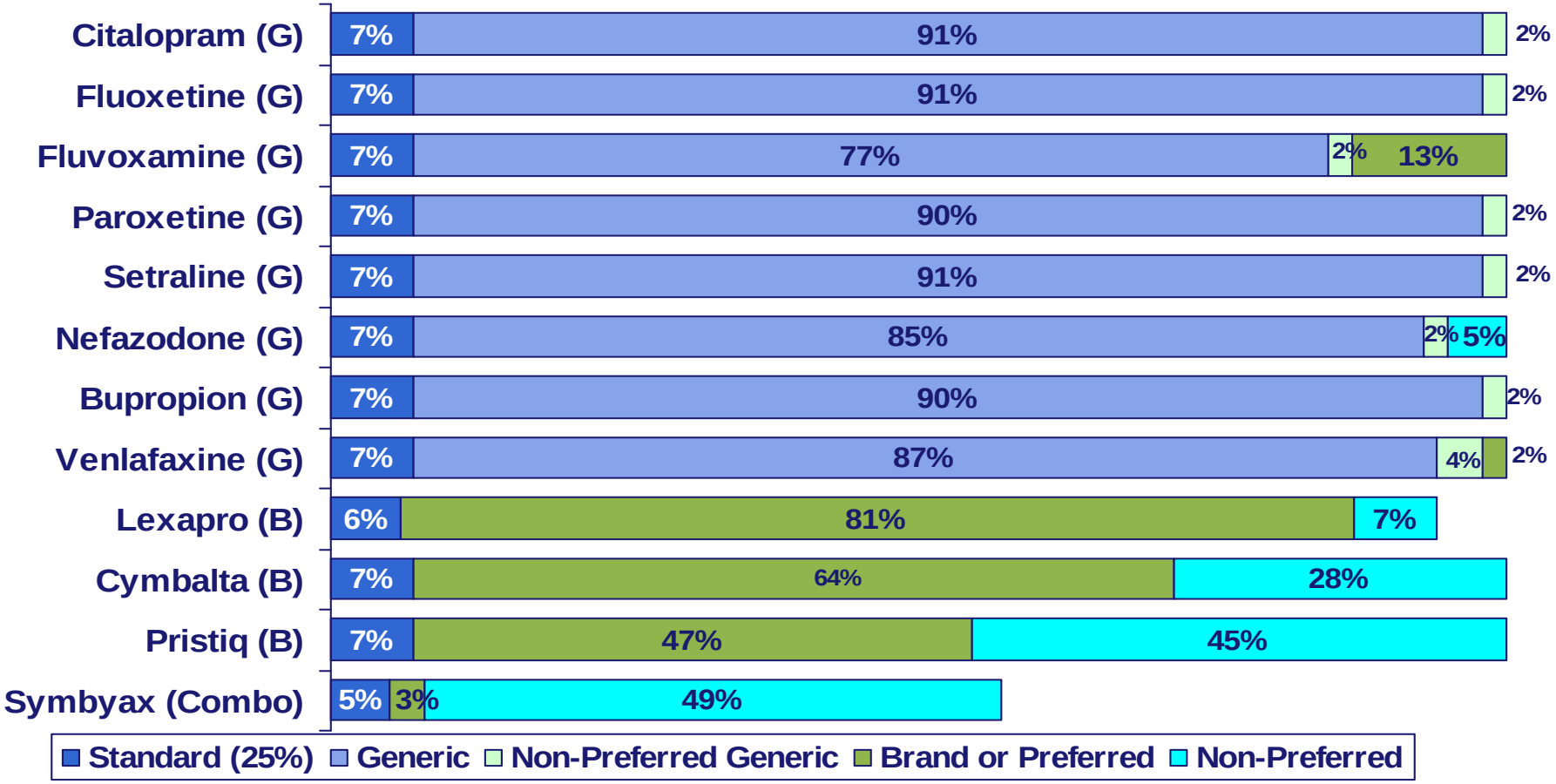
NOTE: Calculations are share of all PDPs, weighted by 2009 enrollments.

Certain Cholesterol Drugs Subject to Step Therapy, 2010



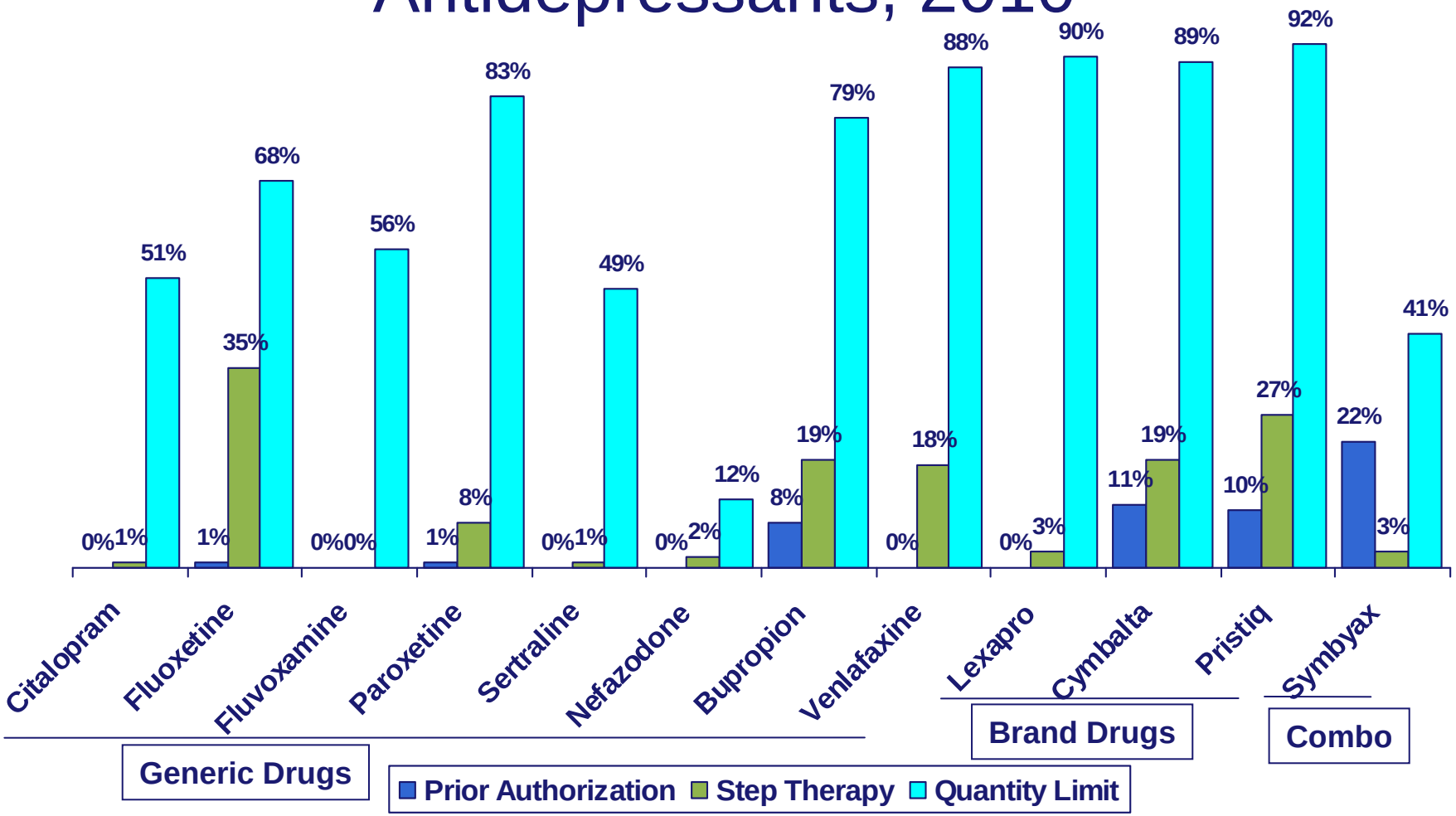
NOTE: Calculations are share of all PDPs listing drug on formulary, weighted by 2009 enrollments.

Most Antidepressants are on Formulary, But Vary in Tier Status, PDPs, 2010



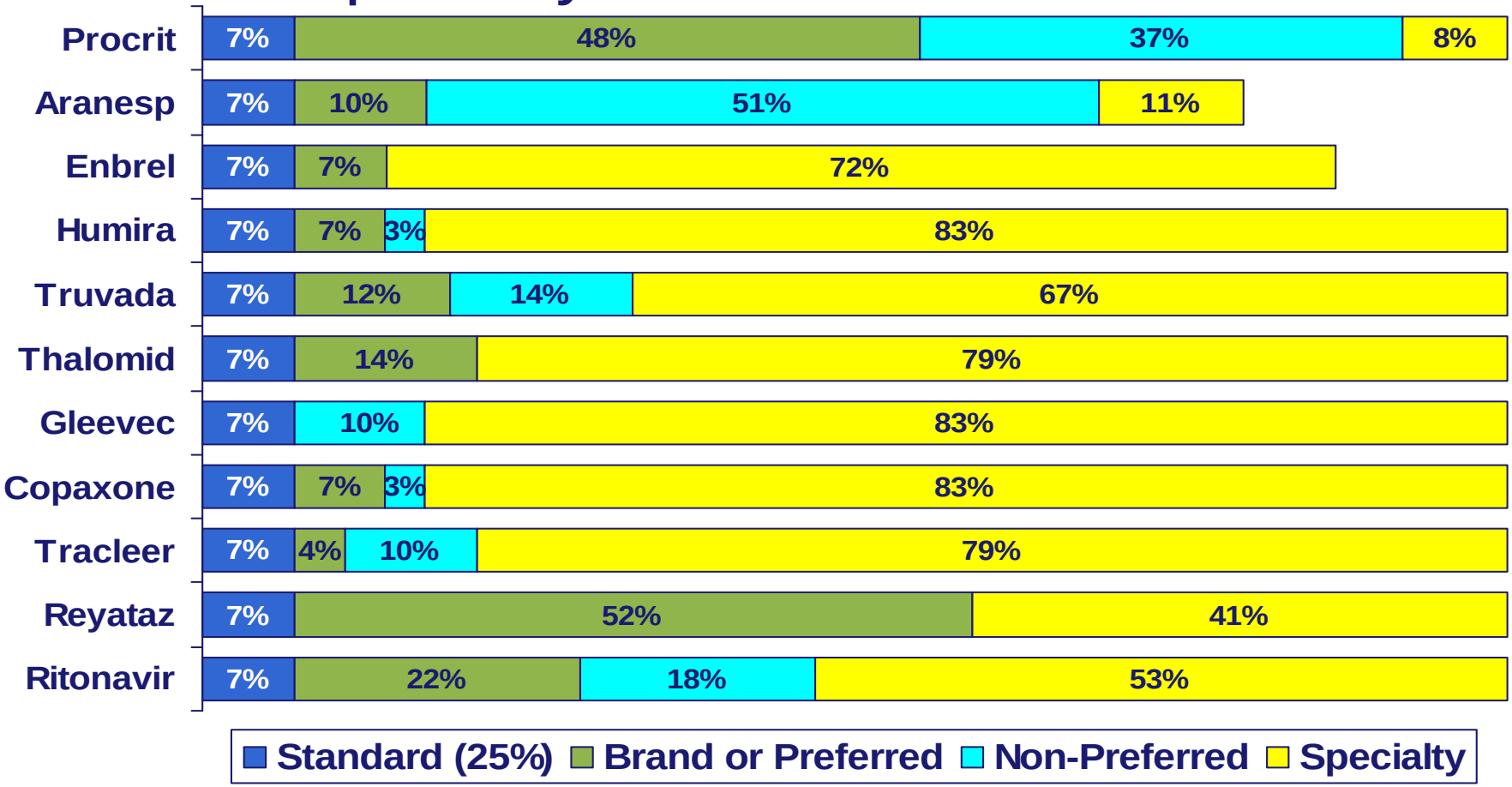
NOTE: Calculations are share of all PDPs, weighted by 2009 enrollments.

Quantity Limits Most Common for Antidepressants, 2010



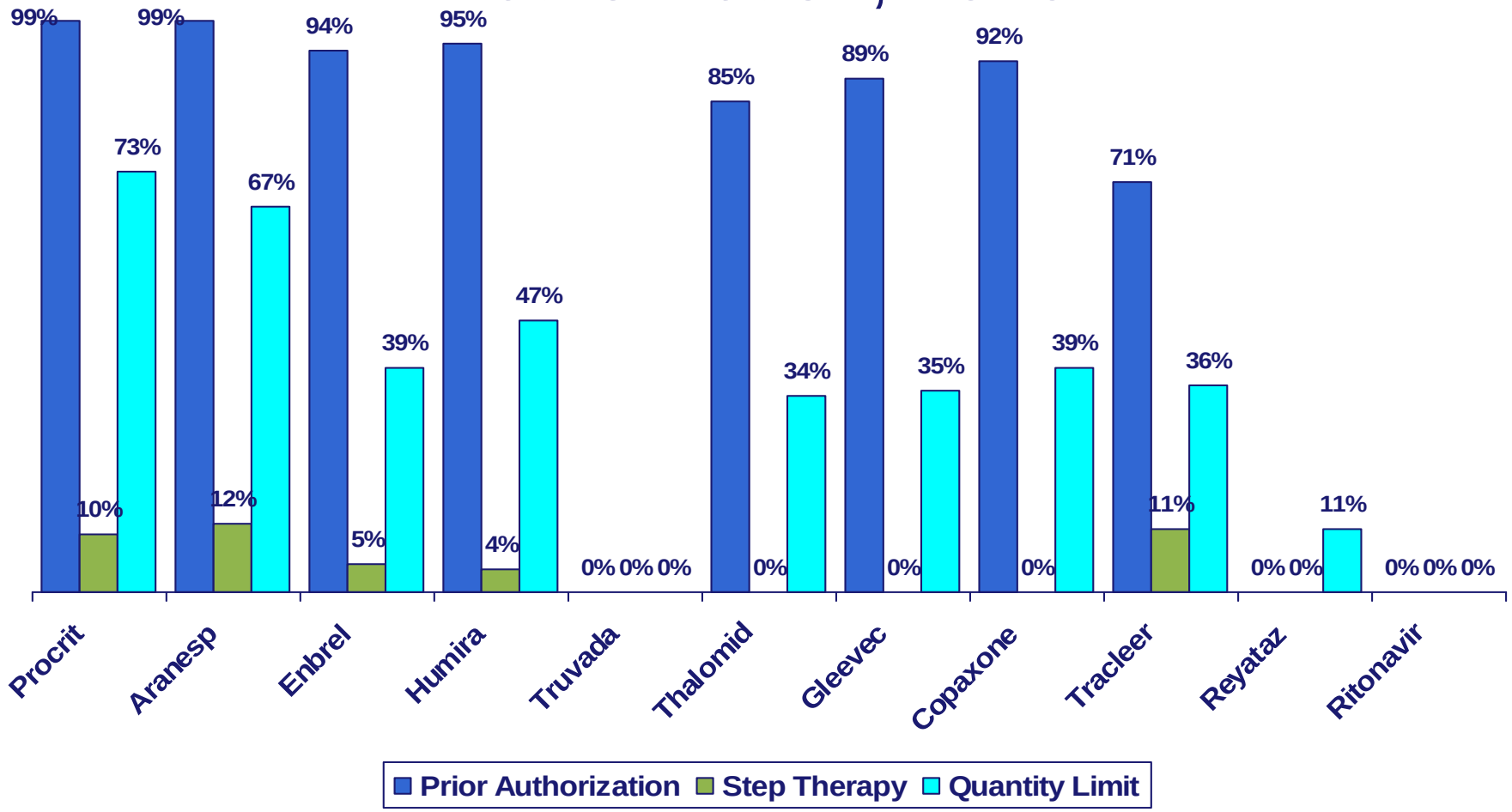
NOTE: Calculations are share of all PDPs listing drug on formulary, weighted by 2009 enrollments.

Expensive Drugs Mostly, But Not Always, on Specialty Tiers, PDPs, 2010



NOTE: Calculations are share of all PDPs, weighted by 2009 enrollments.

Expensive Drugs Often Subject to Prior Authorization, 2010



NOTE: Calculations are share of all PDPs listing drug on formulary, weighted by 2009 enrollments.

Policy Issues: Standardization

- Tiers and tier structures
  - Require accurate tier labels, descriptions
  - Require specific labeling of specialty tiers
  - Consider restricting plans to limited set of tier structures, with room for innovative approaches
- Utilization management
  - More information on UM requirements
  - Require use of standard procedures, forms

Policy Issues: Formulary Performance Measures

- Need for good formulary performance measures
  - Total number of drugs not the right measure
- Options
  - Capture formulary restrictions, perhaps with multiple measures
  - Consider measures at drug class level
  - Measure ability to get *appropriate* exceptions or utilization management approvals

Policy Issues: Drug Classes

- Formulary classification system
  - Require standard classification system
- Use of protected classes
  - Challenge of what classes deserve special treatment vs. existing broad coverage
  - Alternative: plans list all drugs on formulary and negotiate over tier placement
- Within protected classes
  - Clinical justification for non-preferred tier placement and UM restrictions
  - Clinical consideration of treatment of combos, variety of forms/strengths, etc.