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Formulary Access for Patients with Cystic Fibrosis

Background on Avalere's PlanScape® and Methodology for Formulary Analysis

PlanScape® Methodology

- This analysis reviews formulary coverage in the exchanges, with comparisons to 2014, 2015, and other markets, including employer coverage.
- For each year, Avalere analyzed formularies for silver plans participating in all 50 states and the District of Columbia
- Analysis for each year uses the same 2016 drug list, but products launched after October 2014 are only included in calculations after they appear in the dataset
- Formulary data is collected by Managed Markets Insight & Technology, LLC.
- Data is weighted according to unique silver benefit designs by state.
- Analysis excludes plans in which the deductible is equal to the annual out-of-pocket maximum and plans for which there is no cost sharing across service categories.

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Cystic Fibrosis: While Coverage Grew, Specialty Tier Use and High Coinsurance Are Common for CF Treatments

Classes Included:

- Cystic Fibrosis Agents

Coverage for Key Cystic Fibrosis Classes:

- Plans in high-enrollment states except for Florida cover an average of six of nine CF drugs; at a minimum, at least one plan in Michigan and Florida covers only one of these medications
- Coverage for CF innovators increases between 2015 and 2016 exchange plans, but employer plans in 2016 have far higher rates of coverage than what is seen in the exchange market

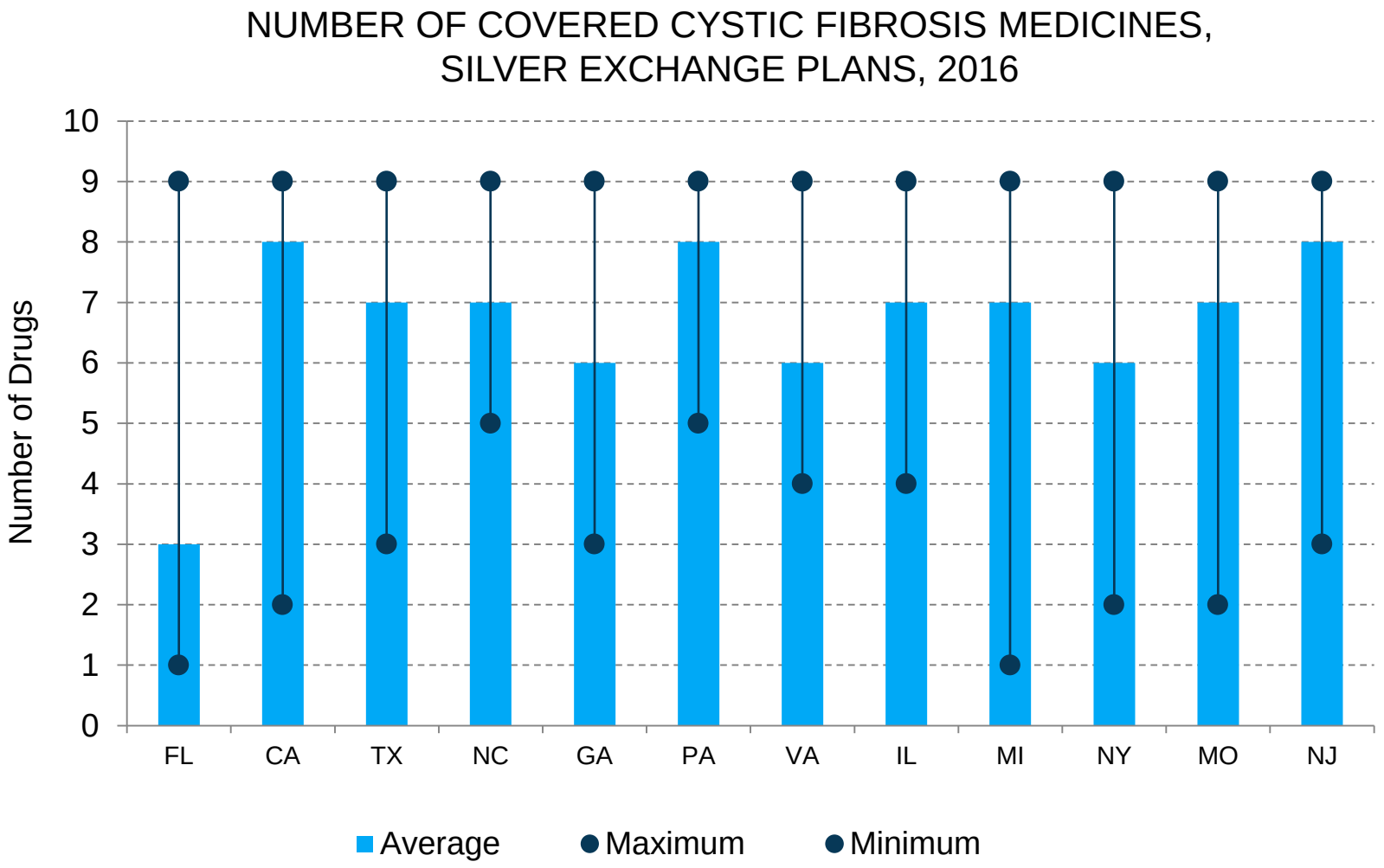
Utilization Management for Cystic Fibrosis Classes:

- Though coverage for CF innovators improves in 2016, rates of UM rise by at least 20 percentage points between 2015 and 2016

Tiering and Cost Sharing for Key Cystic Fibrosis Classes:

- Though exchange plans often cover single-source CF medicines on the specialty tier, rates of specialty tier placement for these medications has decreased since 2014
- A large proportion of plans (48%) place all single source drugs in the class on the specialty tier
- Exchange plans use coinsurance more often than copayments for CF innovators. The average coinsurance used is 38%

Plans in All High-Enrollment States Except for Florida Cover an Average of at Least Six of Nine CF Drugs



Note: Coverage is weighted according to unique plan-state combinations. Sample includes all silver plans offered in 50 states and the District of Columbia. Medical benefit drugs are included in drug counts. Benchmark counts are based on unique chemical entities, while other coverage data counts each brand or generic.
Source: Avalere Health PlanScape®, a proprietary analysis of exchange plan features, April 2016. This analysis is based on data collected by Managed Markets Insight & Technology, LLC.

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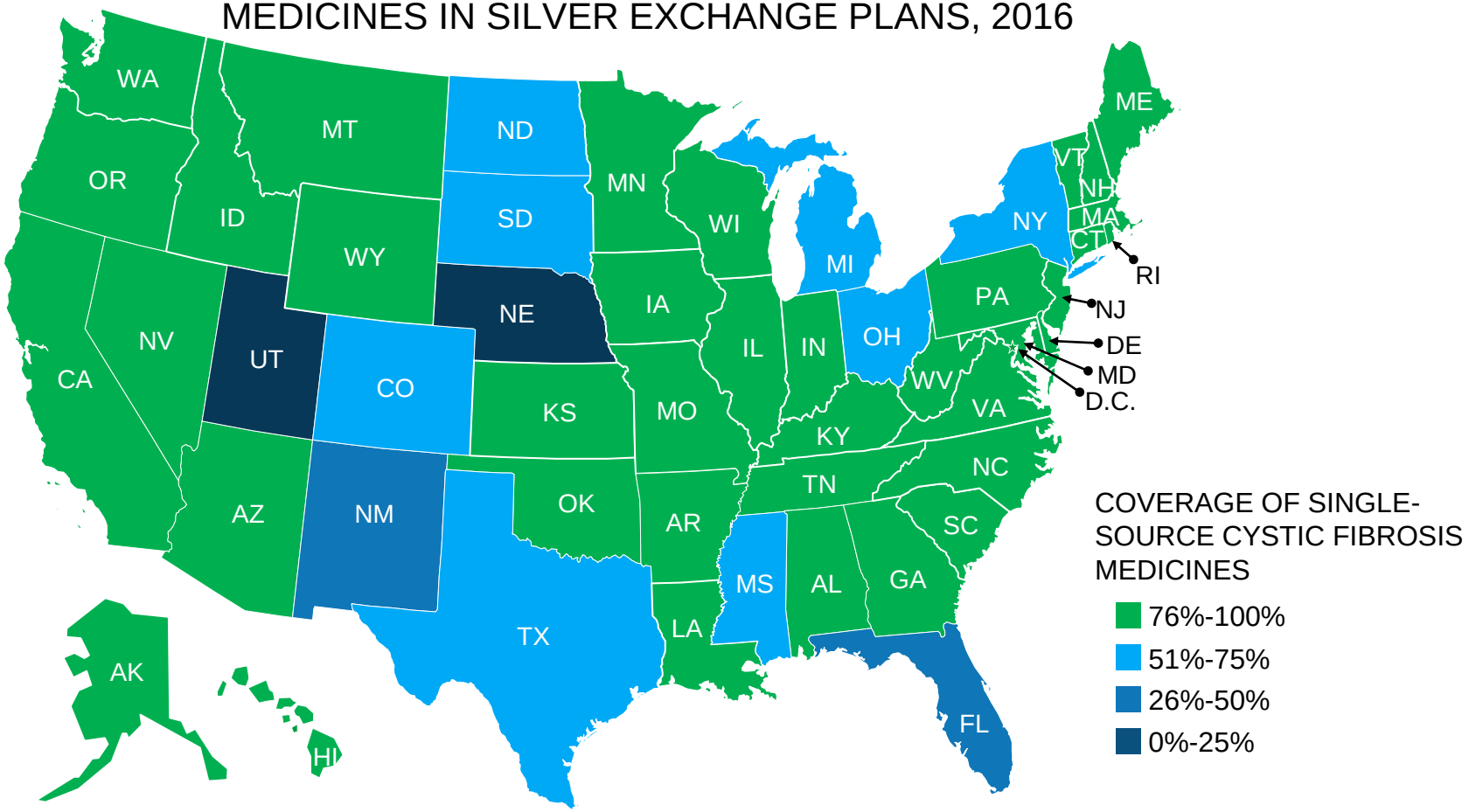
Twelve States Cover Less than Half of Single-Source Cystic Fibrosis Drugs

FORMULARY COVERAGE FOR SINGLE-SOURCE CYSTIC FIBROSIS MEDICINES IN SILVER EXCHANGE PLANS, 2016



Note: Coverage is weighted according to unique plan-state combinations. Sample includes all silver plans offered in 50 states and the District of Columbia. MMIT uses universal tier status rather than “raw” tier numbers to facilitate comparisons across plans and markets. Avalere uses universal tier status for tiering analyses and raw tier status for cost-sharing analyses. For the purpose of this analysis, "coverage" means formulary inclusion. Avalere excluded physician-administered drugs from this analysis, except when comparing to state benchmark minimums.

Source: Avalere Health PlanScape®, a proprietary analysis of exchange plan features, April 2016. This analysis is based on data collected by Managed Markets Insight & Technology, LLC.

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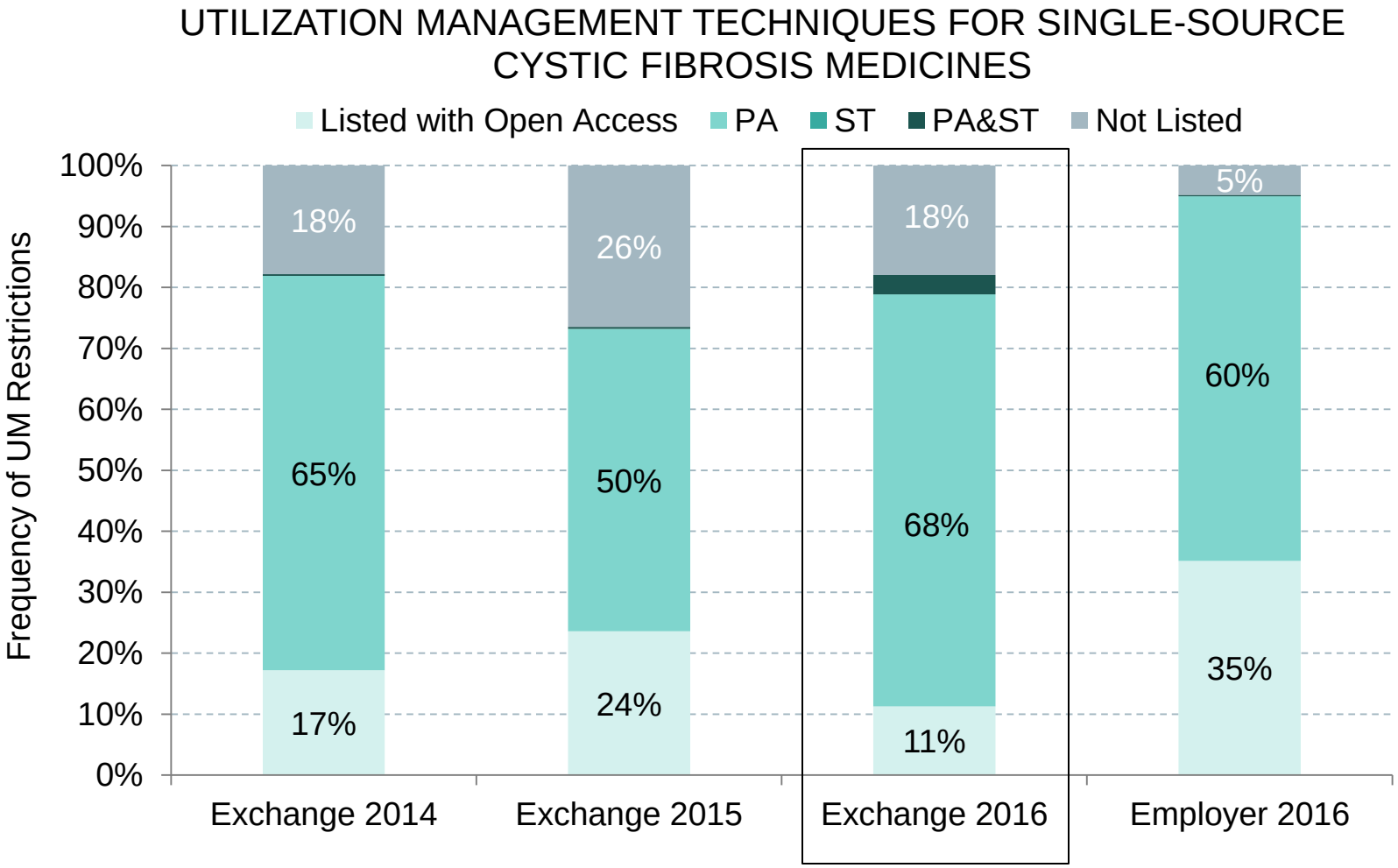
Use of UM for Cystic Fibrosis Innovators Increases as Coverage Increases in 2016 Exchange Plans



*In 2014, neither Kalydeco nor Orkambi appeared on exchange plan formularies.
Note: Coverage is weighted according to unique plan-state combinations. Sample includes all silver plans offered in 50 states and the District of Columbia. For the purpose of this analysis, "coverage" means formulary inclusion. Avalere excluded physician-administered drugs from this analysis, except when comparing to state benchmark minimums.
Source: Avalere Health PlanScape®, a proprietary analysis of exchange plan features, April 2016. This analysis is based on data collected by Managed Markets Insight & Technology, LLC.
PA = Prior Authorization; ST = Step Therapy

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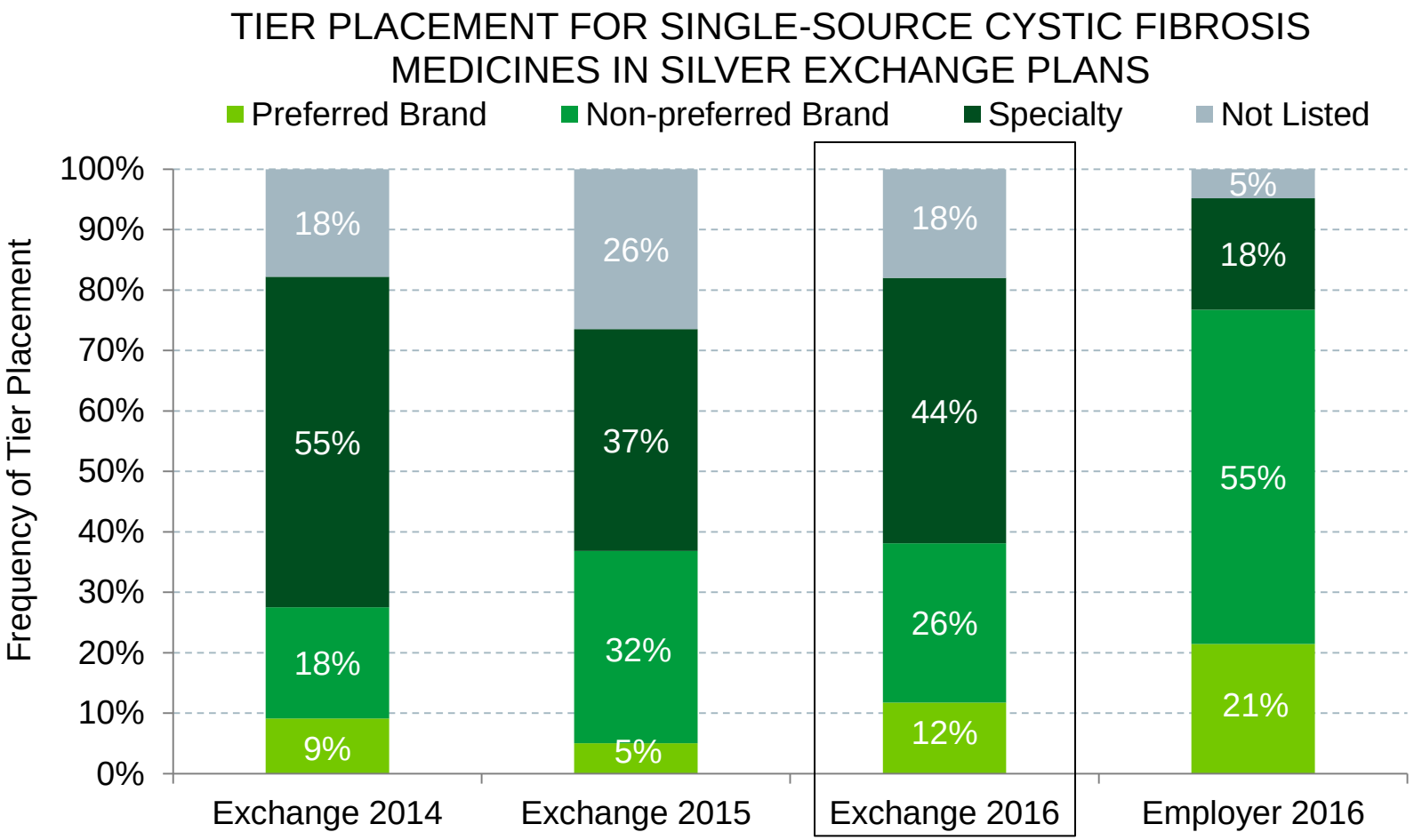
Use of Specialty Tier in Exchanges Is More than Twice As Common than in the Employer Market



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Source: Avalere Health PlanScape®, a proprietary analysis of exchange plan features, April 2016. This analysis is based on data collected by Managed Markets Insight & Technology, LLC.

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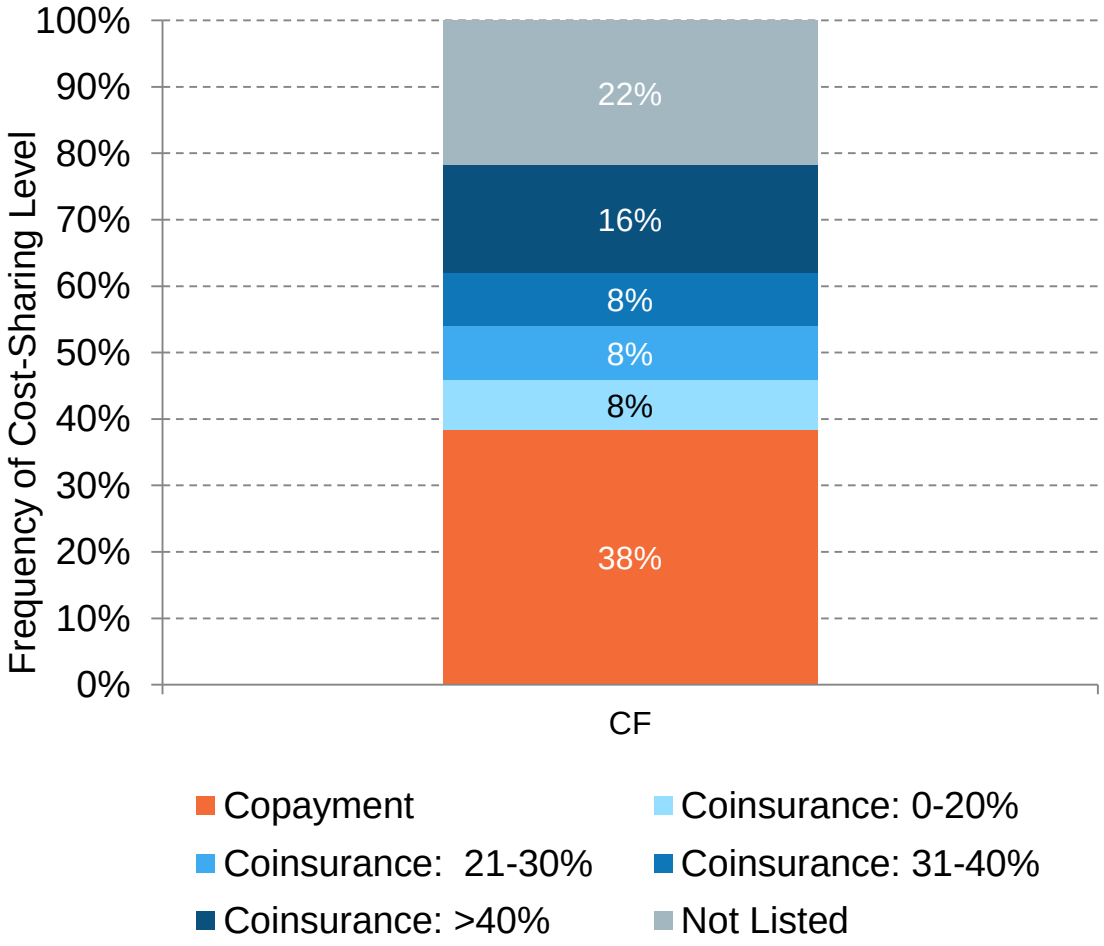
Exchange Plans Use Coinsurance Greater than 30% for CF Innovators About 20% of the Time

COST-SHARING LEVELS FOR SINGLE-SOURCE CYSTIC FIBROSIS MEDICINES, SILVER EXCHANGE PLANS



2016 Copay		2016 Coinsurance
$600	**Maximum**	60%
$92	**Average**	38%
$0	**Minimum**	10%

Note: Coverage is weighted according to unique plan-state combinations. Sample includes all silver plans offered in 50 states and the District of Columbia. For the purpose of this analysis, "coverage" means formulary inclusion. Avalere excluded physician-administered drugs from this analysis, except when comparing to state benchmark minimums.
Source: Avalere Health PlanScape®, a proprietary analysis of exchange plan features, April 2016. This analysis is based on data collected by Managed Markets Insight & Technology, LLC. Excludes instances where cost-sharing amount is unknown.

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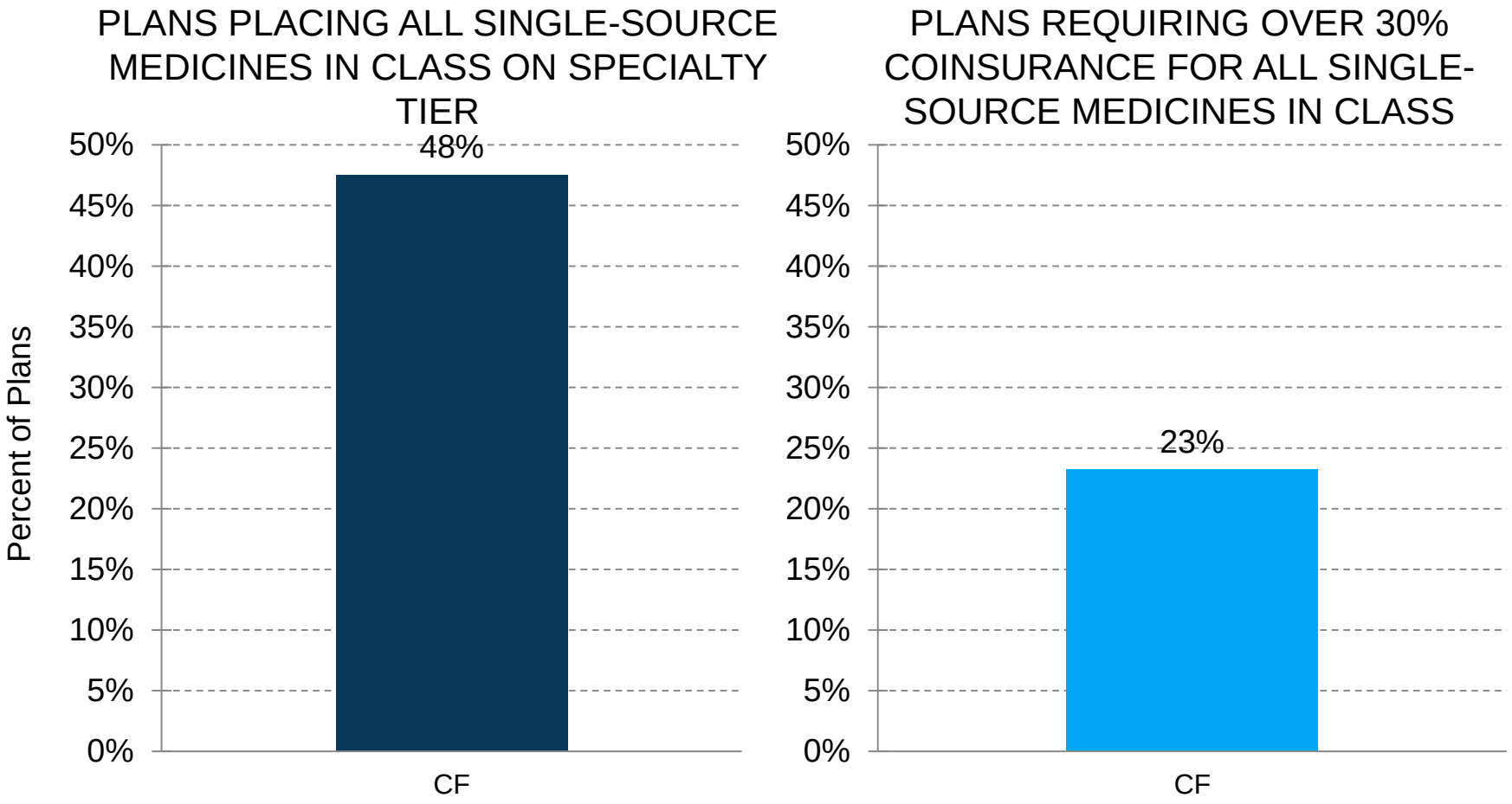
A Large Proportion of Plans Use Specialty Tier or High Coinsurance for All Cystic Fibrosis Innovators



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Source: Avalere Health PlanScape®, a proprietary analysis of exchange plan features, April 2016. This analysis is based on data collected by Managed Markets Insight & Technology, LLC.

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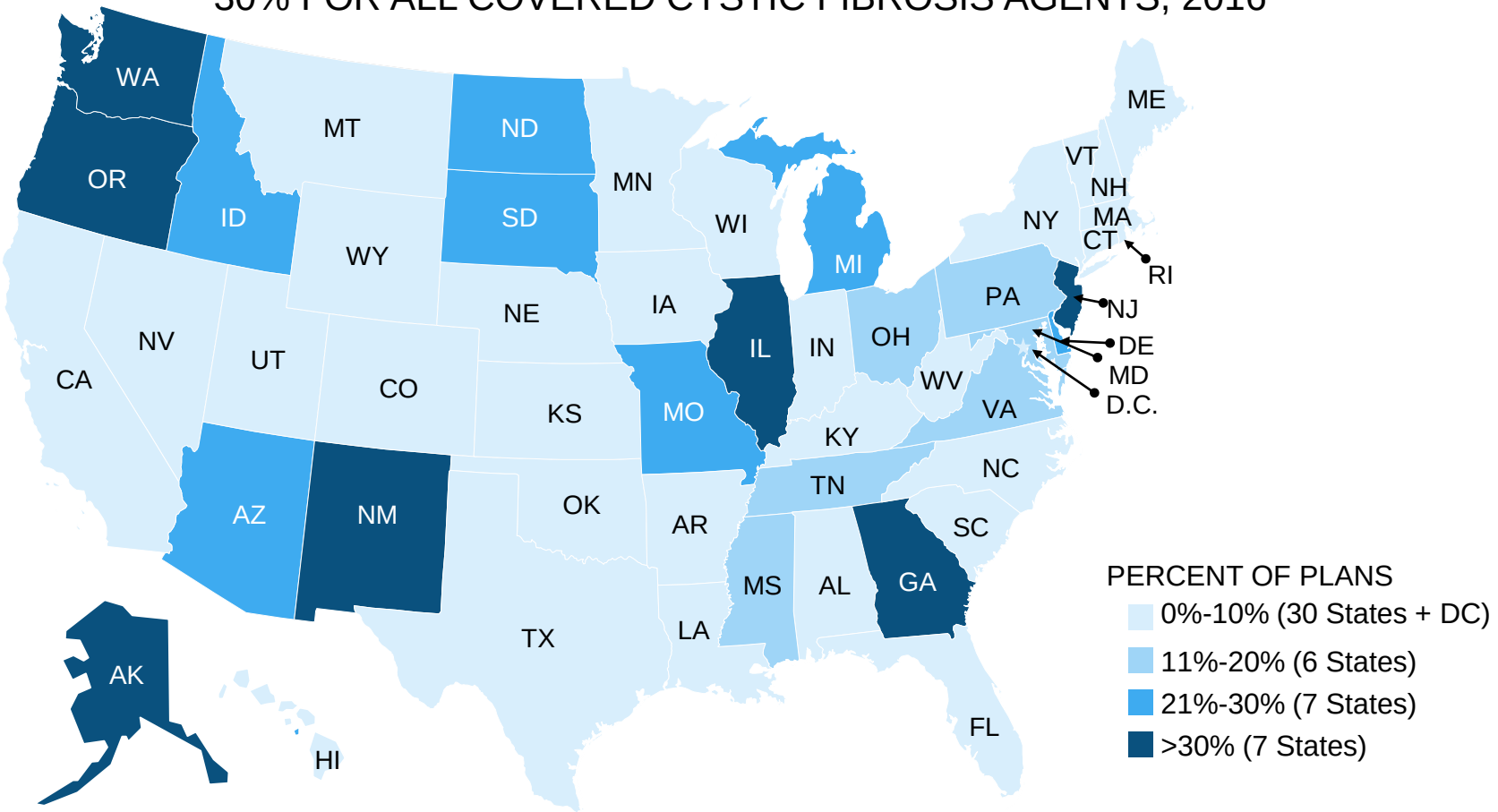
In Thirty States and DC, Fewer than 10% of Plans Require Coinsurance of 30% or More for All Covered CF Drugs

SILVER EXCHANGE PLANS REQUIRING COINSURANCE HIGHER THAN 30% FOR ALL COVERED CYSTIC FIBROSIS AGENTS, 2016



Note: Coverage is weighted according to unique plan-state combinations. Sample includes all silver plans offered in 50 states and the District of Columbia. MMIT uses universal tier status rather than “raw” tier numbers to facilitate comparisons across plans and markets. Avalere uses universal tier status for tiering analyses and raw tier status for cost-sharing analyses. For the purpose of this analysis, "coverage" means formulary inclusion. Avalere excluded physician-administered drugs from this analysis, except when comparing to state benchmark minimums.

Source: Avalere Health PlanScape®, a proprietary analysis of exchange plan features, April 2016. This analysis is based on data collected by Managed Markets Insight & Technology, LLC.

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Methods Appendix

PlanScape® Methodology: MMIT Data

FORMULARY DATA SOURCES

- Formulary data is from Managed Markets Insight & Technology, LLC, an Avalere partner that maintains comprehensive formulary data across a range of payer channels, including the exchanges and employer markets
- Formulary coverage is based on a drug's listing on the plan's published formulary in MMIT's database
    - MMIT gathers data directly from health plans and pharmacy benefit managers, ensuring the accuracy and validity of the formulary data. MMIT's pharmacists and clinicians interpret and standardize formularies
    - In addition, MMIT researchers engage with issuers to understand formulary characteristics, including processes around open and closed formularies, and to understand how plans make coverage decisions so that data reflects accurate consumer experiences for obtaining medications
- Formulary data is based on coverage in all 50 states and DC as of October 2014, October 2015, and April 2016; note that formularies may change throughout the year
- Due to data limitations, 2014 exchange data excludes United Healthcare in NY; 2015 exchange data excludes Health Alliance One in GA; and 2016 exchange data excludes SelectHealth in ID; Health New England in MA; Colorado Choice Health Plans in CO; Minuteman Health in NH; Health Choice in AZ; and Oscar in TX.

PlanScape® Methodology: Benefit Design Dataset

STATES OF FOCUS AND DATA COLLECTION

- For plan benefit designs, Avalere analyzed the FFE landscape file and collected information directly from SBE websites. For 2014 and 2015, Avalere supplemented our SBE data collection with benefit design information from the Robert Wood Johnson Foundation's ACA Silver Plan Dataset
- For SBEs, Avalere collected information for one ZIP code for each rating region[1]
- Avalere made revisions to the FFE landscape file to ensure that only unique plan designs were included in the analysis. That is, duplicate offerings of individual plans were removed prior to analysis when plans shared all benefit design characteristics except premium, county, and region

1 The data for SBEs may not include all plans available since as Avalere only collected information for one ZIP code in each rating region. The same ZIP codes were used in each year for the plan searches.

PlanScape® Methodology: Drug List Creation and Cross-Walking Process

DRUG LIST CREATION

- To develop the list of drugs per class, Avalere consulted the United States Pharmacopeia (USP) Medicare Model Guidelines v5.0 to obtain a listing of the USP Category, USP Class, and Example Drugs
- Additional drugs were identified based on the USP Model v6.0 guidelines, Medi-Span®, and CenterWatch drug databases and internal clinical assessment to reflect updates not reflected in USP v 5.0
- Avalere collaborated with MMIT clinicians and data experts to finalize drug lists according to client-selected USP classes

CROSS-WALKING PROCESS

- Oftentimes, carriers will use the same formulary for all of the exchange plans it offers in a state, but occasionally, issuers will have different formularies if they have more than one exchange plan in the state
- Avalere conducted a manual cross-walking process to align formularies with exchange products using plan documents and other publicly-available plan information
- As a result of this process, exchange plans in the analysis are weighted according to unique silver plans in the market

USP = United States Pharmacopeia

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PlanScape® Methodology: Coverage Statistics and Tiering Data

COVERAGE AND UM

- Although some drugs are covered under a plan's medical benefit, Avalere only includes pharmacy-benefit statistics in this analysis, with the exception of where we compare data to benchmarks
- For drugs available in multiple dosages, MMIT's database utilizes the most commonly utilized dosage
- Coverage and UM statistics are weighted by unique plan-state combinations
- Utilization management data captured includes prior authorization and step therapy, but does not reflect quantity limits

TIERING

- MMIT captures raw status (tier number) and assigns a "universal" tier status, which standardizes formularies into four tiers: generic, preferred brand, non-preferred brand, and specialty
- For the purpose of reporting tiering statistics in this analysis, Avalere used MMIT's universal indicator, as formulary structure varies across plans and universal status allows for easy analysis of drugs within the market
- In contrast, for cost-sharing data, Avalere uses raw tiering information. Avalere excludes cases where raw tiering information is unavailable
- Tiering statistics are weighted by unique plan-state combinations

PlanScape® Methodology: Cost Sharing Methodology

COST-SHARING DATA AND APPROACH

- Because the MMIT dataset does not include cost sharing, Avalere cross-walked MMIT formulary data to its benefit design dataset. The benefit design dataset excludes plans in which the deductible is equal to the annual out-of-pocket maximum, and plans for which there is no cost sharing across service categories
- Summary of Benefits and Coverage documents may relay multiple cost-sharing amounts for a particular formulary tier. Our analysis reflects the highest cost-sharing amount reported for that tier for a 30-day supply purchased at a retail pharmacy
    - Where cost sharing varies based on choice of pharmacy, we selected cost-sharing amounts that apply to preferred pharmacies within a plan's network
- Avalere utilized after-deductible amounts when analyzing cost-sharing categories (e.g., if coinsurance is 10% after meeting a $1,000 deductible, when analyzing costs for the service, Avalere used the 10% coinsurance amount)
- For drugs or services noting cost sharing as the lesser or greater of a copayment or coinsurance amount, Avalere consistently used the coinsurance amount (e.g., $100 or 20% whichever is greater). For drugs or services with coinsurance amounts up to a copayment cap (e.g., 25% coinsurance up to $300), Avalere used the coinsurance amounts

PlanScape® Methodology: Comparison Markets

PLAN AND FORMULARY COUNTS

- Exchange data is presented at the plan level, representing each carrier's unique benefit designs offered in a state
  - Carriers often use the same formulary for multiple plans (i.e., cost sharing varies by plan, but coverage, tiering, and UM do not)
  - Therefore, each individual exchange formulary may be counted more than once, based on the number of unique plans (i.e., cost-sharing designs) relying on that formulary
- In contrast, employer data is reported at the formulary level; each formulary counts once in the dataset regardless of the number of cost-sharing designs using that formulary

Market	Plans	Formularies	States
Exchange	**1,571**	249	51
Employer	9,079	**569**	51

Note: **Orange** numbers indicate counts used in analysis.

UM = Utilization Management

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