

BACKGROUND & OBJECTIVE

- Clinical outcome assessments (COAs) are instruments used to measure how patients feel, function, or survive. Although COAs are widely used in clinical trials to assess treatment efficacy, little is understood about their role in specialty drug coverage¹.
- Our study examined the frequency, types, and application of COAs in US commercial health plans' specialty drug coverage policies.

METHODS

Data Source

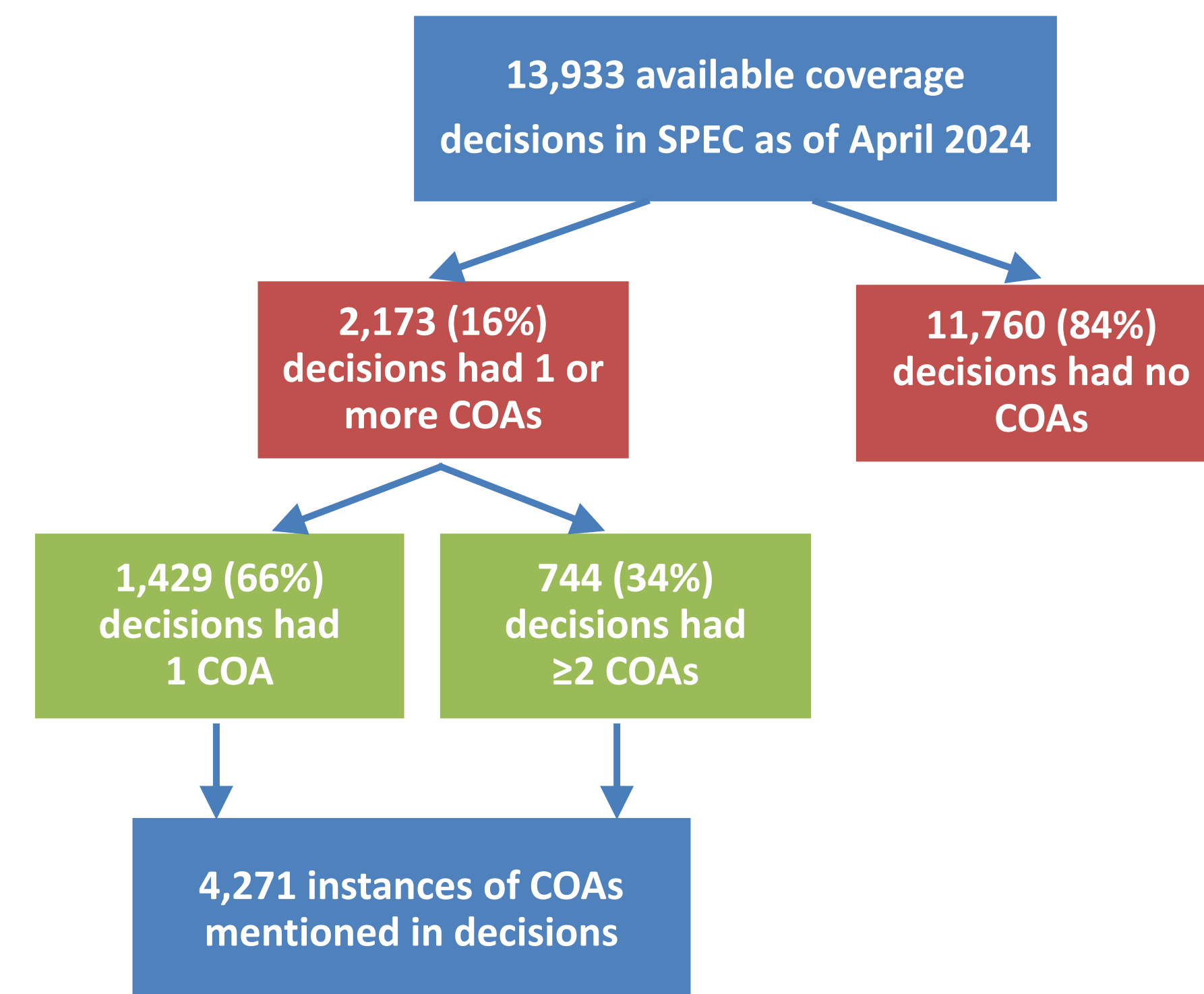
- We used coverage information as of April 2024 from the Tufts Medical Center Specialty Drug Evidence and Coverage (SPEC) Database, which tracks specialty drug coverage decisions from 18 large US commercial health plans.

Analyses

- We reviewed coverage decisions to identify disease-specific COAs and categorized them in three ways:
 1. **Timepoint:** Whether the COA was required at initial coverage or reauthorization.
 2. **Type:** Patient-reported outcomes (PRO), observer-reported outcomes (ObsRO), clinician-reported outcomes (ClinRO), performance outcomes (PerfO), composites (i.e., multiple COA types), or COA—unspecified (an outcome is required, but no specific instrument is named)².
 3. **Application** (initial coverage only): We categorized how COAs were used at the time of initial coverage into four applications: documenting baseline disease status to enable future measurement of change; confirming a diagnosis; determining disease severity thresholds to limit or enable access to treatment; and defining meaningful treatment response criteria required for continued therapy.

RESULTS

Figure 1. Use of COAs in Specialty Drug Coverage Decisions



- Of the coverage decisions in SPEC, 2,173 (16%) included at least one COA, and 744 (34% of those) included multiple COAs. Each instance in which a COA appeared in a coverage decision was counted, resulting in 4,271 total COA mentions included in our analysis (Figure 1).
- In initial coverage text, COAs were most often used to limit access/enable access (50%) (Figure 2).

Figure 2. Application of COAs in Initial Coverage Decisions (n= 2,043)

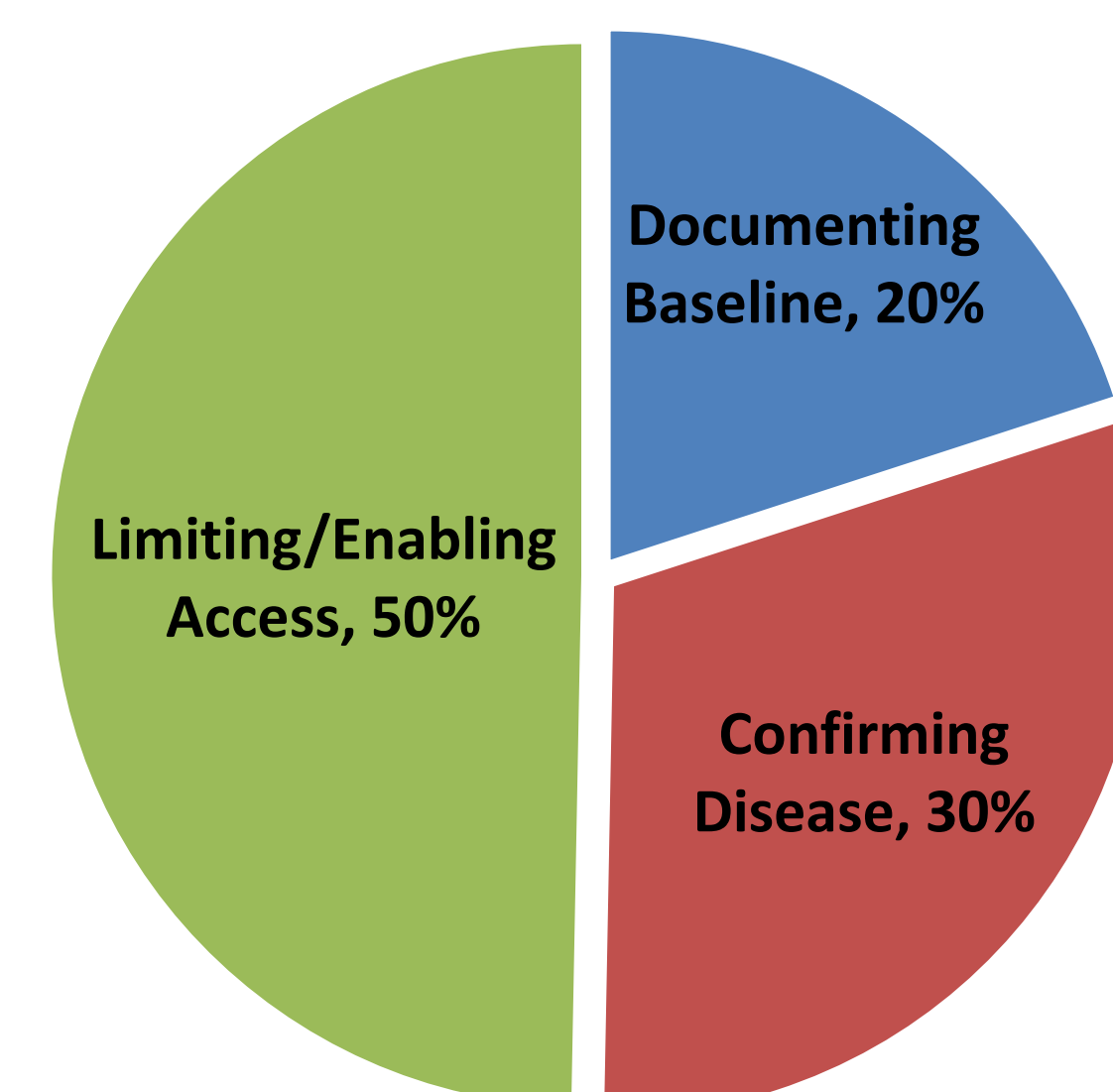
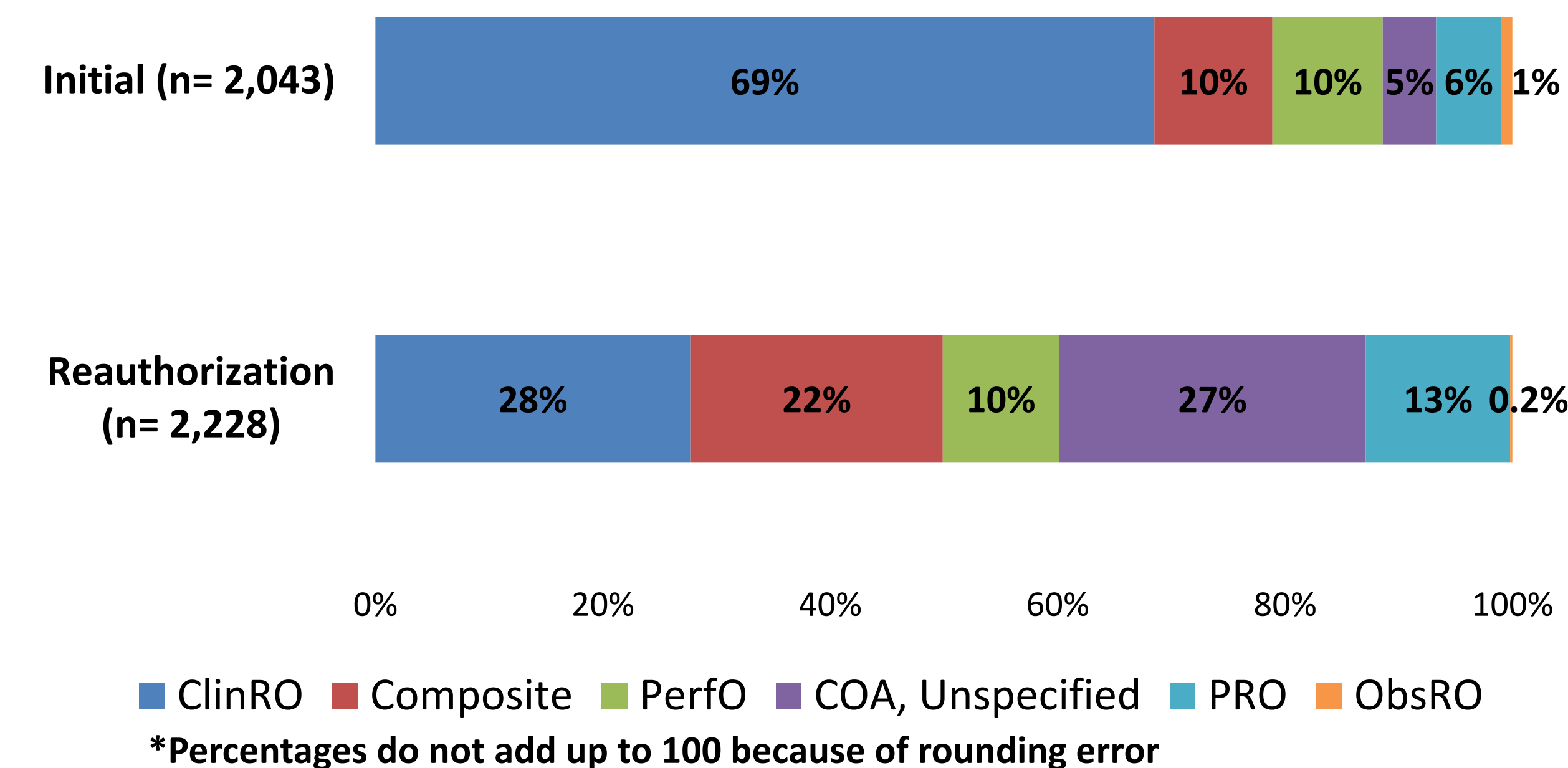
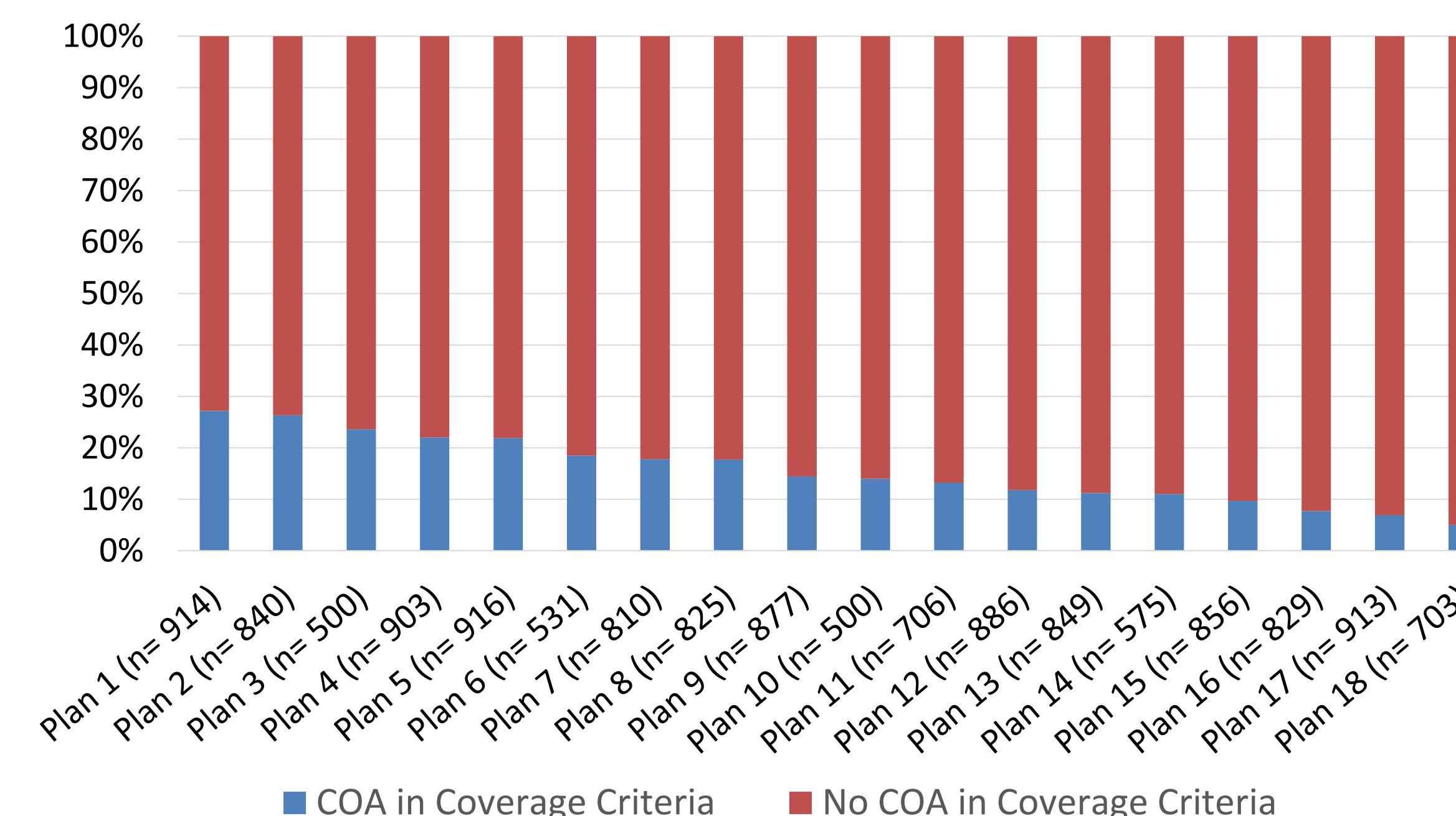


Figure 3. COA Types in Initial vs. Reauthorization Coverage Text



- 48% of COAs appeared in health plans' *initial* coverage criteria, the majority of which were ClinROs (69%) (Figure 3).
- The remaining 52% of COAs were featured in *reauthorization* criteria, with ClinROs (28%), COA—unspecified (27%), and composites (22%) being the most common types (Figure 3).
- Use of COAs varied across health plans, ranging from 5% to 27% of coverage decisions (Figure 4).

Figure 4. Proportion of Health Plan Policies Including COAs (n= 13,933)



CONCLUSION

- This is the first study to document how US commercial health plans use COAs in specialty drug coverage decisions.
- ClinROs were the most commonly used COAs, underscoring the central role of providers in determining treatment access.
- PROs were used infrequently, suggesting a missed opportunity to incorporate the patient voice in assessing treatment outcomes that matter when determining coverage decisions.
- COAs were most often applied in initial coverage criteria to limit or enable access to treatment.
- Use of COAs varied considerably across health plans.
- Further research is needed to understand how health plans determine when and how to use COAs, and what role these assessments play in shaping access to therapy.

REFERENCES

1. US Food and Drug Administration (FDA). Clinical outcome assessments (COA): frequently asked questions. 2019; <https://www.fda.gov/about-fda/clinical-outcome-assessment-coa-frequently-asked-questions>. Accessed 2/20/24.
2. Mapi Research Trust. ePROVIDE COA Database; <https://eprovide.mapi-trust.org/>.

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CONTACT

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<https://lillyscience.lilly.com/congress/ispor2025>