# Characteristics of Early Adopters of a Two-Drug Regimen (Dolutegravir/Rilpivirine) for Treatment of Human Immunodeficiency Virus Type 1 in the United States

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### BACKGROUND

- Combination antiretroviral therapies (ART) have resulted in longer lifespans and an aging population of people living with HIV (PLWH).<sup>1, 2</sup>
- Two-drug ART regimens minimize drug exposure, reduce risks for adverse effects, drug-drug interactions, and long term toxicities.<sup>3, 4</sup>
- In 2017, Juluca<sup>®</sup> (dolutegravir/rilpivirine; DTG/RPV), the first complete treatment regimen containing only two antiretroviral (ARV) drugs in a single tablet to treat HIV-1 was approved for use in ART-experienced patients currently suppressed on a stable regimen with no history of treatment failure or resistance to either DTG or RPV.<sup>5</sup>

**OBJECTIVE:** Characterize the early utilization of DTG/RPV in the US

### METHODS

#### **Study Population**

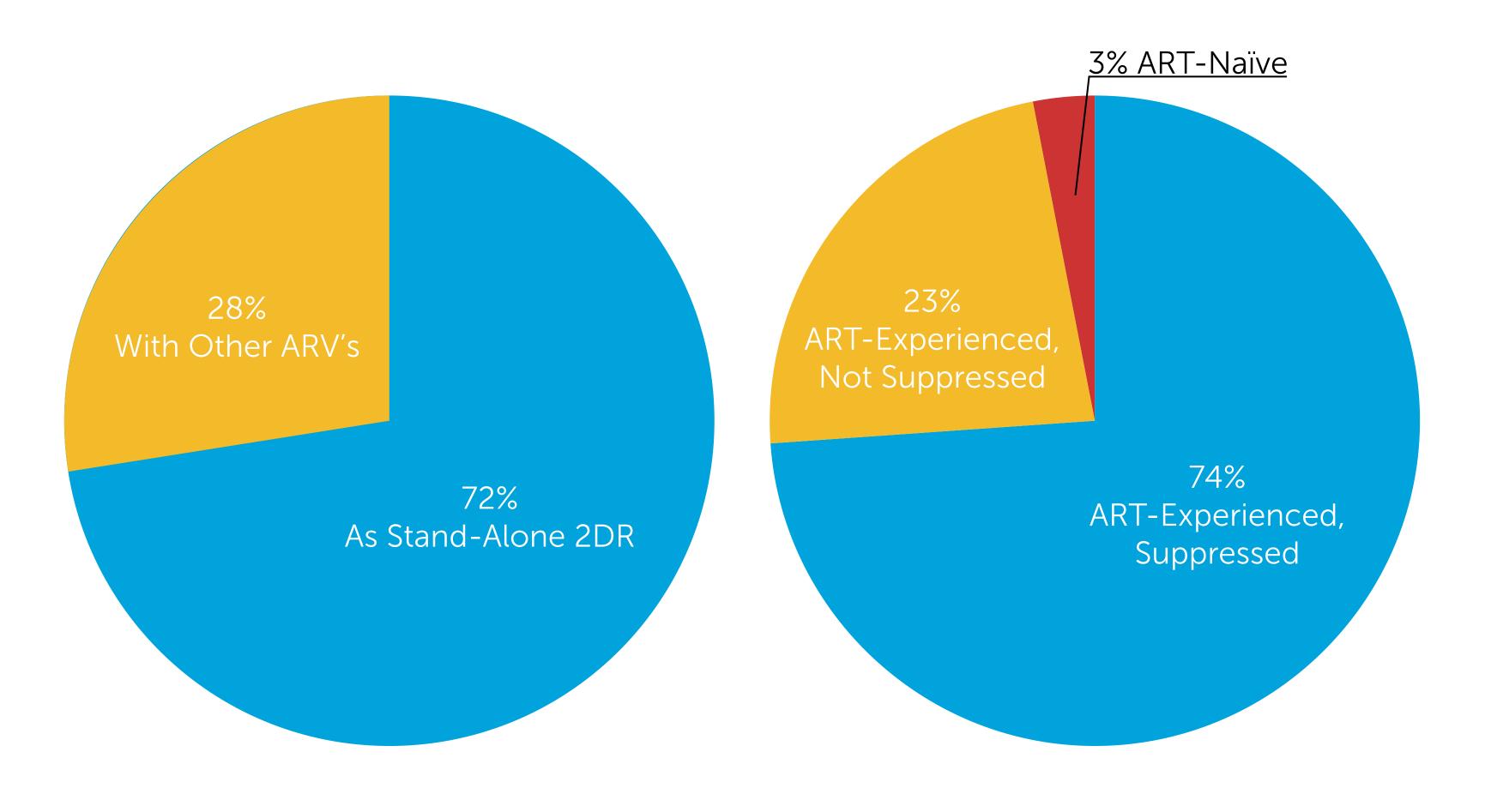
- Observational clinical cohort analysis
  - Data from the Observational Pharmaco-Epidemiology Research and Analysis (OPERA) database
  - Prospectively collected electronic medical record (EMR) data
  - More than 90,000 PLWH from 84 clinics across 18 states, District of Columbia, and Puerto Rico
  - Collaboration of over 400 caregivers nationwide
- Inclusion Criteria:
- HIV-1-positive
- $\geq$  18 years of age
- Prescribed DTG/RPV between January 1, 2018 and June 30, 2018
- Exclusion Criteria:
  - PLWH co-infected with HIV-2
- Previously initiated DTG/RPV as part of a clinical trial

#### Data Analysis

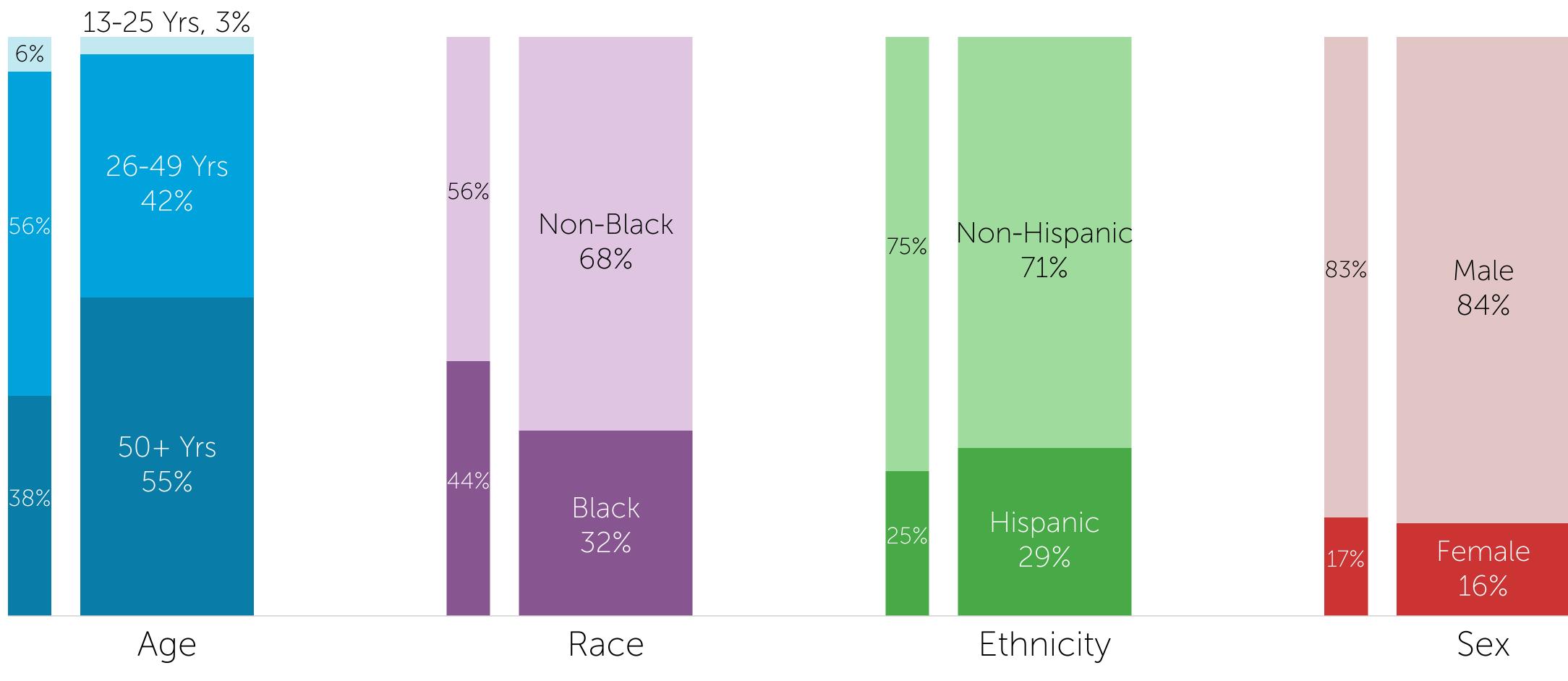
- Index: Date of DTG/RPV initiation
- Follow-up period: January 1, 2018 to June 30, 2018
- Overall and stratified analyses were conducted
- Patient demographic characteristics were described at index
- Clinical and treatment characteristics were described using a baseline of 12 months unless otherwise specified.

## RESULTS

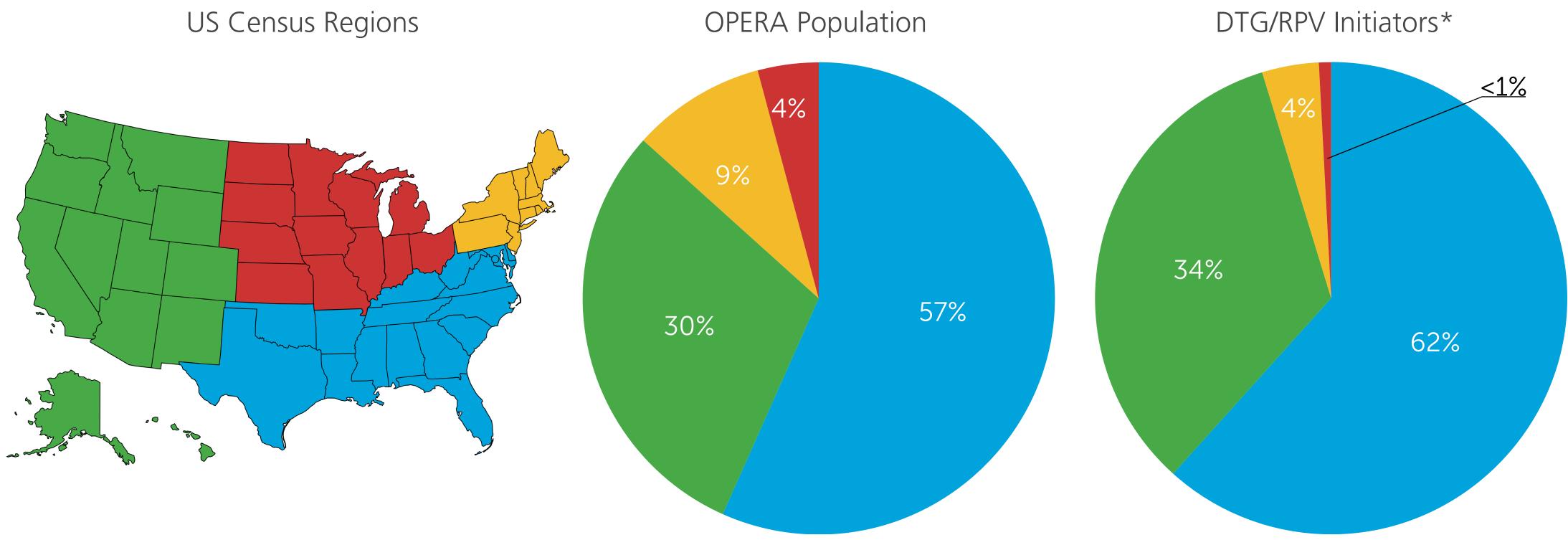
Figure 1. DTG/RPV Initiators by Regimen Components, ART History, and Virologic Status at Initiation (N=456)



#### Figure 2. Demographic Characteristics of DTG/RPV Initiators (n=456, thick bars) Compared to the Active OPERA **Population (N=46,177, thin bars)**

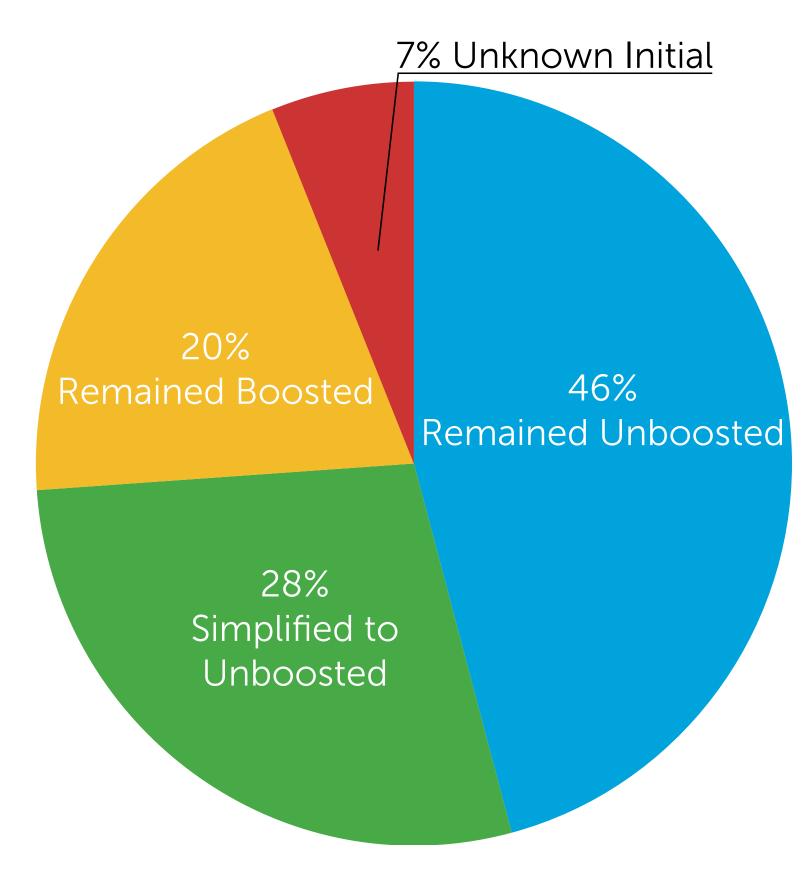


#### Figure 3. Regional Distribution of DTG/RPV Initiators within OPERA



\* Sum of percentages may not exactly equal 100 due to rounding.

Figure 4. Regimen Simplification Among DTG/RPV Initiators\*



\* Sum of percentages may not exactly equal 100 due to rounding



#### Figure 5. Clinical Characteristics of DTG/RPV Initiators at Baseline\*

 $500 \ge CD4 > 200 \text{ cells/}\mu\text{L}$  $CD4 \leq 200 \text{ cells/}\mu\text{L}$  6% Viral Load <50 cps/mL Viral Load 50-199 cps/mL

Initiated ART After 2014 Initiated ART 2011-2014 Initiated ART Before 2011

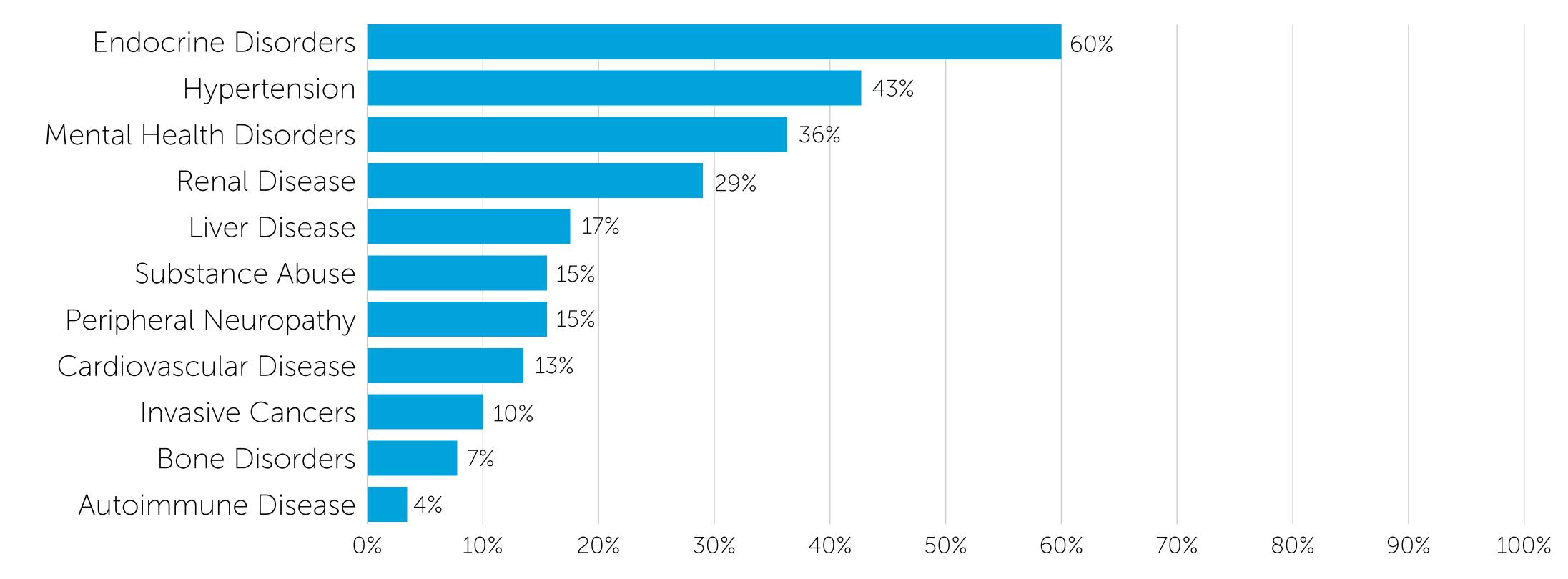
Viral Load ≥200 cps/mL



#### Figure 6. Baseline Comorbidities in DTG/RPV Initiators

10%

20%



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### DISCUSSION

- Most patients were ART-experienced, initiating DTG/RPV as a stand-alone, twodrug regimen.
- At initiation, most patients had undetectable viral loads or had viral loads between 50 and 199 copies/mL. Few patients had viral loads  $\geq$ 200 copies/mL.
- Regimens were frequently simplified.
- Comorbidity was prevalent: 86% of patients had  $\geq 1$  comorbid condition. 60%  $\geq 1$ endocrine disorder, 43% hypertension, 36% a mental health disorder and 29% renal disease.
- In patients living with HIV-1 infection and other concomitant chronic illnesses, DTG/RPV may be an important option for clinician's needing to simplify an HIV regimen
- Limitation: While the OPERA cohort follows up to 7% of the HIV epidemic in the US, it may over- or underestimate specific subpopulations.

### **KEY FINDINGS:**

Early initiators of DTG/RPV were primarily treatmentexperienced individuals older than 50 years of age with virologic and immunologic control but challenged by significant comorbid conditions.

#### REFERENCES

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https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm586305.htm.

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