



# Injectable PrEP Coverage and Access

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- June 2019 – U.S. Preventive Services Task Force (USPSTF) issued [Grade A recommendation](#) for PrEP
  - Most private health plans in California are now required to cover both PrEP medication and related clinical services such as provider visits and labs without cost sharing – including Apretude®
- October 2019 – Governor Newsom signed into law [Senate Bill 159](#)
  - Prohibits most private health plans from requiring “prior authorization” or “step therapy” for individuals to access PrEP – including Apretude®

- 2/3 of private health plans in California are regulated by the California Department of Insurance (CDI) or Department of Managed Health Care (DMHC)
- [CDI](#) and [DMHC](#) guidance requires all state-regulated health plans to cover both PrEP medication and related clinical services without cost sharing
- Required to cover Apretude® and Descovy® without prior authorization or step therapy (also cannot be designated as “non-formulary”)
  - Some plans may require documentation of medical necessity (e.g., weight)
- Can require prior authorization or step therapy on brand name Truvada® as long as generic Truvada covered without these restrictions
- **December 2021 CDI [guidance](#) confirms coverage requirements for Apretude®**

# Self-Insured Employer Health Plans

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- 1/4 of private health plans in California – known as self-insured employer health plans – are regulated by the federal Department of Labor
- Under federal [guidance](#), these plans are required to cover both PrEP medication and related clinical services without cost sharing
- Allowed to require prior authorization or step therapy for PrEP, but the process must be “expedient” and allow individuals to start PrEP on the same day as their visit or negative HIV test
- If the prior authorization or step therapy request is approved, PrEP medication must still be covered without cost sharing
- **Federal guidance does NOT yet apply to Apretude® so coverage and cost sharing may vary – USPSTF update underway (expected end of year)**

- Less than 1 in 10 private health plans in California – known as “grandfathered” health plans – were in existence when the ACA was passed and have stayed basically the same since then
- These plans are not subject to some patient protections under the ACA, thus not required to cover PrEP medication or related clinical services without cost sharing
- They are also allowed to require prior authorization or step therapy for individuals to access PrEP
- **Coverage and cost sharing for Apretude® may vary**

# Submitting a Complaint

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- If a health plan is not in compliance, individuals are strongly encouraged to [submit a complaint](#) to DMHC
- DMHC strongly encourages individuals to file a complaint form electronically through the [online option](#) to process the request as quickly as possible.
- If you contact DMHC and they find that your health plan is under the jurisdiction of CDI, they will forward your complaint to CDI
- You do not need to file a complaint with your health plan first
- You need to file a completed and signed [Authorized Assistant Form](#) to submit as complaint on behalf of a patient
- If you have a self-insured employer health plan, you can contact the federal Department of Labor at 1-866-444-3272 or [submit a complaint online](#)

- California's Medicaid program – known as [Medi-Cal](#) – covers PrEP medication and related clinical services without cost sharing
- For individuals earning less than 138% of the federal poverty level (approximately \$17,609 for a single individual)
- Medi-Cal does not require prior authorization/"Treatment Authorization Request" (TAR) or step therapy for individuals to access PrEP
- **Apretude<sup>®</sup> added to the Medi-Cal Rx "Contract Drug List" as of May 1st, 2022**
  - Also available under Medi-Cal medical benefit

- [Medicare](#) is a public insurance program for older adults and people with disabilities
- **Currently Medicare coverage of Apretude® is limited**
  - Apretude® expected to be covered under Medicare Part B – expect zero cost share with favorable “National Coverage Determination” (NCD) and USPSTF recommendation
  - Some Medicare Advantage plans that include prescription drug coverage (Part D) may opt to cover it as a pharmacy benefit
- Financial assistance programs available to help cover any cost sharing



- ViiVConnect Assistance Program

- Reside in one of the 50 states, the District of Columbia, or Puerto Rico
- Household income <500% of the Federal Poverty Level
- Not eligible for Medicaid

**And either:**

- Have no prescription drug coverage, or
- Have a Medicare Part B, Medicare Part D, or Medicare Advantage Plan, and have spent at least \$600 or more on out-of-pocket prescription expenses during the current calendar year, or
- Have a private health plan limited to generic-only coverage, outpatient use only, or therapeutic class exclusion (non-coverage) of a drug

- “Buy-and-Bill”
  - Provider purchases Aprelude® from a specialty distributor and maintains an inventory of the drug on site
  - Following administration of the drug, provider submits a reimbursement claim to the patient’s health plan
  
- “White Bagging”
  - Provider submits prescription for Aprelude® to a specialty pharmacy within ViiV’s specialty pharmacy network
  - Specialty pharmacy processes claim and ships product to the provider
  - Once Aprelude® is received by the provider, it can only be administered to the patient who was prescribed the drug

- Medical vs. Pharmacy Benefit
  - Health plans likely to cover Aprelude<sup>®</sup> as a medical benefit because it needs to be administered in a clinical setting
  - Plans may also cover it as a pharmacy benefit, or as both a medical and pharmacy benefit
- Any cost sharing requirements will depend on how Aprelude<sup>®</sup> is covered
  - Drugs covered as a medical benefit often require a flat co-insurance rate (e.g., 20% of the total cost of the medication) after the plan deductible requirement has been met



# Questions?

Thank You!

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