QUANTITY LIMIT PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**KALETRA**
(generic)	**(lopinavir/ritonavir)**
Status: CVS Caremark Criteria	***COVID19***
Type: Quantity Limit; Post Limit Prior Authorization	***Ref # 3695-M***

FDA APPROVED INDICATION[1]
Kaletra is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients (14 days and older).

Compendial Use[2]
Coronavirus disease 2019 (COVID-19)

INITIAL STEP THERAPY

- If the patient has an ICD diagnosis code for human immunodeficiency virus (HIV), then the requested drug will be paid under that prescription benefit and quantity limits will not apply.
- If the patient has filled a prescription for at least a 30 day supply of Kaletra within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit and quantity limits will not apply.

If the patient does not meet the above initial step therapy criteria, then initial quantity limits will apply (see initial quantity limit chart below).

INITIAL QUANTITY LIMIT**

LIMIT CRITERIA

Drug	2 Month Limit*	3 Month Limit*
Kaletra 200-50 mg	56 tablets / 50 days	Does Not Apply
Kaletra 100-25 mg	112 tablets / 50 days	Does Not Apply
Kaletra 400-100 mg / 5 mL oral solution	160 mL / 50 days	Does Not Apply

**The duration of 50 days is used for a 60-day fill period.*

***If the patient is requesting more than the initial quantity limit supply, then the claim will reject with a message indicating that the patient can receive a quantity sufficient to treat COVID-19 and then prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.*

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the treatment of human immunodeficiency virus
  [Note: Initial quantity limits allow for a sufficient quantity of the requested drug to treat coronavirus disease 2019 (COVID-19). A maximum of 112 tablets of 100-25mg, 56 tablets of 200-50mg, or 160 mL of 400-100mg/5mL oral solution is available without prior authorization.]

RATIONALE

If the patient does not meet the above initial step therapy criteria, then initial quantity limits will apply. Kaletra is available as 100-25 mg tablets, 200-50 mg tablets, and 400-100 mg/5mL oral solution. The dosing used for coronavirus disease 2019 (COVID-19) is 400 mg/100 mg twice daily.[2] Therefore, the quantity limit is set at 112 tablets of the 100-25 mg strength, 56 tablets of the 200-50 mg strength, and 160 mL of the 400-100 mg/5mL oral solution.

If initial quantity limits are exceeded, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

Since the initial quantity limits are sufficient to treat COVID-19, the post limit criteria will not approve additional quantities for this indication.

REFERENCES

1. Kaletra [package insert]. North Chicago, IL: AbbVie, Inc.; December 2019.
2. Clinical Pharmacology [database online]. Tampa, FL: Elsevier Inc. Copyright 2020. https://www.clinicalkey.com/pharmacology/. Accessed March 2020

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