Use of Cabotegravir and Rilpivirine Tablets to Manage Planned Interruption of Monthly Injection Dosing with Long-Acting Cabotegravir Plus Rilpivirine

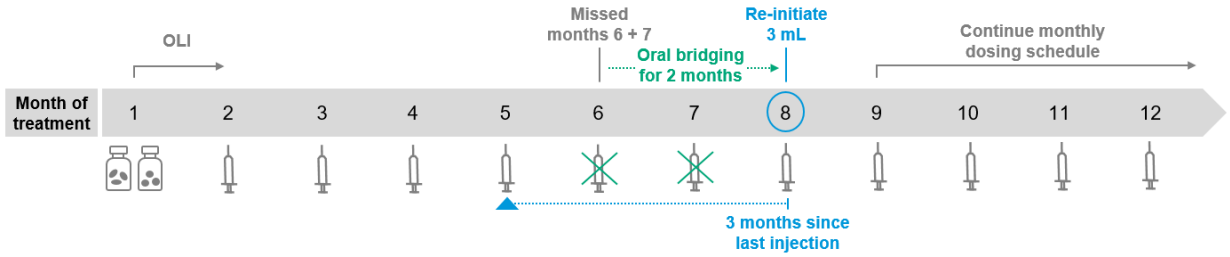
Summary

- Adherence to the monthly injection dosing schedule is strongly recommended.[1]
- If a patient plans to miss a scheduled injection visit by more than 7 days, prescribe daily oral therapy with any fully suppressive antiretroviral regimen for up to 2 months to replace 2 missed injection visits until injections are resumed.[1]
- The first dose of daily oral therapy should be taken approximately 1 month after the last dose of long-acting cabotegravir plus rilpivirine (CAB + RPV LA). Injection dosing should be resumed on the day oral dosing completes.[1]
- Resumption or re-initiation of long-acting injections should be based on the time since the last injection.[1]

HOW TO USE ORAL BRIDGING[1]

1. Prescribe oral cabotegravir 30 mg + oral rilpivirine 25 mg once daily with a meal with instructions to start dosing at the time of the planned missed injection visit and continue until injection dosing is resumed. Alternatively, any fully suppressive antiretroviral regimen may be used.
2. Take the last daily oral doses which ever regimen is used on the same day injection dosing is resumed.
3. Refer to Table 1 below to decide how to resume or re-initiate CAB + RPV LA dosing based on the time since the last injection.

Figure 1. Example of the Use of Oral Bridging to Cover Planned Missed Injections[1]



NOTE: use of the oral lead-in (OLI) is optional to assess tolerability. The healthcare provider and patient may choose to proceed directly to injectable therapy. If used, the OLI should be taken for approximately 1 month (at least 28 days).

Table 1. Injection Dosing Recommendations After Oral Therapy[1]

Time since missed injection	Recommendation
≤1 month	Resume with 400 mg (2 mL) of cabotegravir and 600 mg (2 mL) of rilpivirine intramuscular monthly injections as soon as possible.
>1 month	Re-initiate the patient with 600 mg (3 mL) of cabotegravir and 900 mg (3 mL) of rilpivirine intramuscular injections then continue to follow the 400-mg (2-mL) cabotegravir and 600-mg (2-mL) rilpivirine intramuscular monthly injection dosing schedule.

CLINICAL TRIAL DATA

ATLAS[2,3]

Through Week 48, 98% of injections were given ±7 days from the planned dosing visit.

Seven patients utilized oral bridging with CAB and RPV between injections during the Maintenance Phase, with durations ranging from 4 to 29 days in length. In all the patients, pre-dose CAB and RPV concentrations just prior to resuming injection dosing reflected the contribution from preceding oral doses and were within the range of exposures expected following oral dosing. All patients successfully continued injection dosing following temporary oral bridging while maintaining virologic control (< 50 copies/mL) and with no safety events of clinical concern.

FLAIR[4,5]

Through Week 96, 97% of injections were given ±7 days from the planned dosing visit.

Nine patients utilized oral bridging with CAB and RPV between injections during the Maintenance Phase with durations ranging from 4 days to 61 days in length. In all the patients, pre-dose CAB and RPV concentrations just prior to resuming injection dosing reflected the contribution from preceding oral doses and were within the range of exposures expected following oral dosing. All patients successfully continued injection dosing following temporary oral bridging while maintaining virologic control (plasma HIV-1 RNA < 50 copies/mL) and with no safety events of clinical concern.

Impact of COVID-19 on Administration Visits

Data from 1744 patients who were active participants in phase 2 and 3 clinical trials during the initial stage of the COVID-19 pandemic (December 1, 2019 through September 15, 2020) were included in an assessment of the impact of the pandemic on the ability of patients to adhere to administration visits.[6]

Overall, 93% of patients (n=1615) were able to maintain their administration schedule.[6] Oral therapy with CAB and RPV was used in 5% of patients (n=94) and alternative oral antiretroviral therapy (ART) was used by 2% (n=27).

The most common regimens used as alternative oral ART were dolutegravir plus rilpivirine (41%) and abacavir/dolutegravir/lamivudine (37%).[6]

Overall, the median (interquartile range) duration of oral therapy was 51 days (27 to 69).[6] Through October 19, 2020, 91% of patients who were transitioned to oral therapy had restarted injections with CAB + RPV LA.

No suspected or confirmed virologic failures were observed as a result of visits impacted by COVID-19.[6]

This information is scientific and non-promotional in nature and is not intended for further distribution. Selection of references follows principles of evidence-based medicine and, therefore, references may not be all inclusive.

REFERENCES

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