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Cost-effectiveness of cabotegravir-rilpivirine LA vs. lamivudine/abacavir/dolutegravir and vs. bictegravir/emtricitabine/tenofovir in the treatment of HIV+ patients in Italy, a short-term analysis

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Introduction/Summary

In Italy, the management of HIV-1 includes the use of long-acting injectable (LA) therapy with cabotegravir (CAB) and rilpivirine (RPV) as a maintenance option. However, no analysis has yet been conducted in Italy to compare the cost-effectiveness of this therapy with standard regimens such as lamivudine/abacavir/dolutegravir (3TC/ABC/DTG) and bictegravir/emtricitabine/tenofovir (BIC/FTC/TAF). The primary objective of this analysis is to evaluate the incremental cost-effectiveness ratio (ICER) and incremental cost-utility ratio (ICUR) of using CAB LA + RPV LA compared to current antiretroviral regimens (CAR).

Study Design

A deterministic incremental cost-effectiveness analysis (ICER) and incremental cost-utility analysis (ICUR) were conducted over a one-year time horizon, based on 48-week efficacy and utility data from the considered studies, adopting the perspective of the Italian National Health Service. While the evaluation period is short for a chronic disease, the results nonetheless provide valuable insights into the treatment's acceptability in Italy.

The analysis was performed on two randomized phase 3 clinical trials: the pooled FLAIR+ATLAS study and the SOLAR study, both with a 48-week duration.

Methods

Efficacy was assessed through the percentage of virologic suppression achieved in the FLAIR+ATLAS and SOLAR studies. Utility was evaluated using a weighted average of values associated with each study's reference population, stratified by CD4+ cell count.

Cost analysis encompassed treatment and adverse event management costs. Treatment cost data were sourced from the Lombardy Region's 2023 Diagnostic Therapeutic Care Pathway (PDTA) for people living with HIV.

For the CAB LA + RPV LA therapy, the annual cost was derived by summing the cost of Rilpivirine and Cabotegravir (excluding 10% VAT) and the cost of 7 pairs of injections administered within the first year. The cost of CAR therapies was calculated similarly, with the exclusion of injection costs due to their oral administration route.

Results of 1

SOLAR

Table 1 details the calculation of the ICER and ICUR for the SOLAR study at 48 weeks.

Table 1 **Calculation of ICER and ICUR for the SOLAR study at 48 weeks**

	CAB + RPV LA	CAR
Efficacy	90,16%	92,83%
Utility	0,6823	0,6945
Treatment cost (VAT excluded)	€ 6.604,09	€ 6.467,04
Cost of adverse events	€ 425,74	€ 573,89
Total costs	€ 7.029,83	€ 7.040,93
ICER	**€ 376,31**	
ICUR	**€ 415,96**	

Analysis of SOLAR study demonstrated no significant difference in cost-effectiveness between long-acting and oral HIV therapies.

The ICER and ICUR nearly zero, indicating neither therapy confers a substantial economic advantage.

These findings are crucial for clinical and health policy decision-making, since suggest both options are economically viable. This allows additional factors, such as patient preference to be considered in treatment selection.

Results of 2

FLAIR + ATLAS

The cost associated with CAR therapy was calculated similarly, resulting in a final cost of €6.959,52.

In summary, Table 2 details the calculation of ICER and ICUR, providing a comprehensive overview of the economic evaluation for this study.

Table 2 **Calculation of ICER and ICUR for the FLAIR+ATLAS study at 48 weeks**

	CAB + RPV LA	CAR
Efficacy	93,10%	94,40%
Utility	0,7922	0,7889
Treatment cost (VAT excluded)	€ 6.604,09	€ 6.959,52
Cost of adverse events	€ 934,71	€ 721,67
Total costs	€ 7.538,80	€ 7.681,19
ICER	**€ 10.953,11**	
ICUR	**€ 19.896,80**	

The analysis of the 48-week pooled FLAIR+ATLAS study data clearly demonstrates that the adoption of long-acting (LA) therapy is an advantageous choice, both in terms of cost-effectiveness and cost-utility, compared to the traditionally employed therapeutic regimen.

- The total costs of CAB+RPV LA therapy are slightly lower than CAR therapy.
- The clinical benefits and efficacy of LA therapy outweigh the cost incurred to modify the therapy itself, resulting in a favorable incremental cost-effectiveness ratio (€10.953,11) and incremental cost-utility ratio (€19.896,80), highlighting its potential added value in the current therapeutic landscape.

Conclusion

While LA therapy may demonstrate slightly lower efficacy compared to oral therapy, it offers a distinct advantage in cost management due to reduced administration frequency and lower adverse event rates. Although initial costs may be higher, the overall cost of LA therapy is reduced over time.

Additionally, a significant decrease in injection site reactions (ISRs) is observed over time, indicating improved long-term tolerability. This trend is confirmed in research conducted in the SOLAR study, where a decline in ISRs over time is observed (month 1 [49%]; month 6 [30%]; month 12 [11%]).

Notably, the economic evaluation does not consider patient preference and adherence, which are significantly improved with LA therapy due to reduced pill burden and increased discretion. Furthermore, the injectable administration allows for closer monitoring and intervention by healthcare professionals, ensuring treatment continuity and adherence.

In summary, while slightly less efficacious, LA therapy offers economic and practical advantages over oral therapy, including improved long-term tolerability, patient satisfaction, and adherence, ultimately contributing to enhanced quality of life for people living with HIV.

References

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