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Bridging the Gap: How Early Access Shapes Pricing and Reimbursed Populations in France

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1 OBJECTIVES

France's early access programmes (AAPs; ATU, AP1, AP2) allow patient access to innovative therapies prior to marketing authorisation and health technology assessment (HTA). AAPs are often the first market access hurdle in Europe but their influence on final pricing and access is not formally defined. This analysis evaluates differences in indications and pricing between AAP and formal reimbursement in France.

2 METHODS

Therapies granted early access (AP1/AP2) and subsequently reimbursed in France between 2021 and 2025 were identified using the Haute Autorité de Santé (HAS) and the *Ministère du Travail, de la Santé, des Solidarités et des Familles* databases. Products were limited to first indication launches, were required to have completed AP1/AP2 and been fully reimbursed. AAP list prices and indications were sourced from the ANSM website. Launch list prices and indications and time to reimbursement were sourced from GlobalData. Products were categorised by therapeutic area, and differences in population scope and pricing between early access and launch were assessed.

3 RESULTS

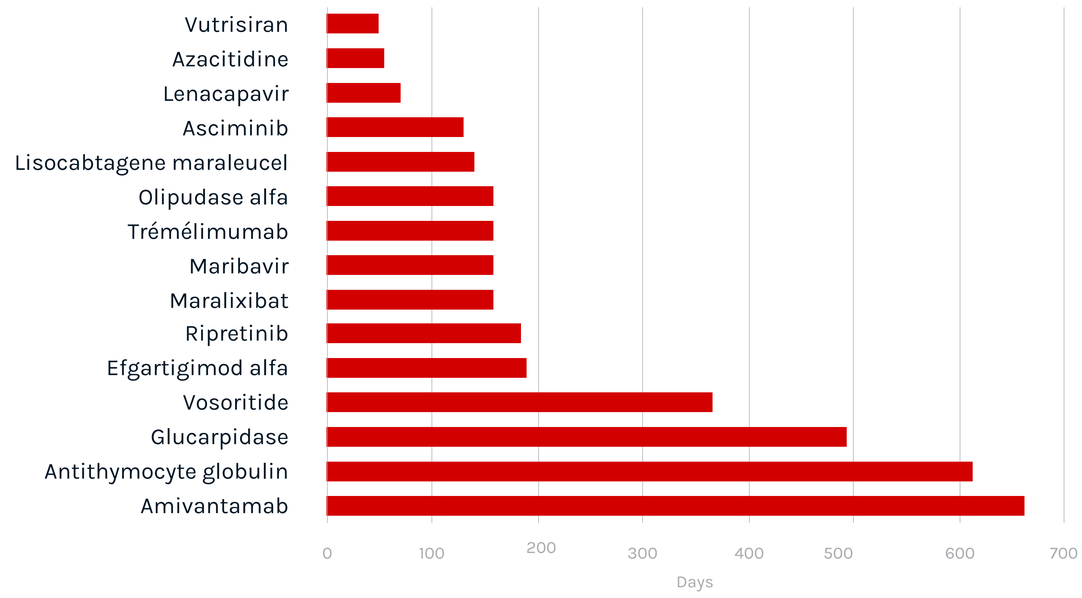
Among 15 therapies granted early access shown in **Table 1**, 47% of therapies were for oncology indication, 40% orphan diseases and 13% infectious diseases. Differences between AAP and launch populations were observed in 4 cases. Among the products exhibiting differences between AAP and their approved launch indications, all 4 of them have broader target populations at launch, with variations in characteristics such as age, disease subtypes, and patients' ineligibility for available therapies.

Table 1. Launch Overview of AAP Products (2021-2025)

PRODUCT NAME	LAUNCH DATE	THERAPEUTIC AREA	DIFFERENCES BETWEEN AAP AND REIMBURSED POPULATIONS	PRICE CHANGE
Amivantamab	2024	Oncology	No	Unchanged
Anti-thymocyte globulin (equine)	2024	Orphan	No	Increased
Glucarpidase	2023	Oncology	No	Decreased
Maralixibat	2023	Orphan	No	Increased
Maribavir	2023	Infectious Disease	No	Unchanged
Trémélimumab	2023	Oncology	No	Decreased
Lenacapavir	2023	Infectious Disease	Ineligibility for available therapies	Unchanged
Vutrisiran	2023	Orphan	Ineligibility for available therapies	Unchanged
Lisocabtagene maraleucel	2023	Oncology	Patient sub-types	Decreased
Efgartigimod	2023	Orphan	No	Decreased
Vosoritide	2022	Orphan	Age	Unchanged
Ripretinib	2022	Oncology	No	Decreased
Asciminib	2022	Oncology	No	Increased
Olipudase alfa	2022	Orphan	No	Increased
Azacitidine	2021	Oncology	No	Unchanged

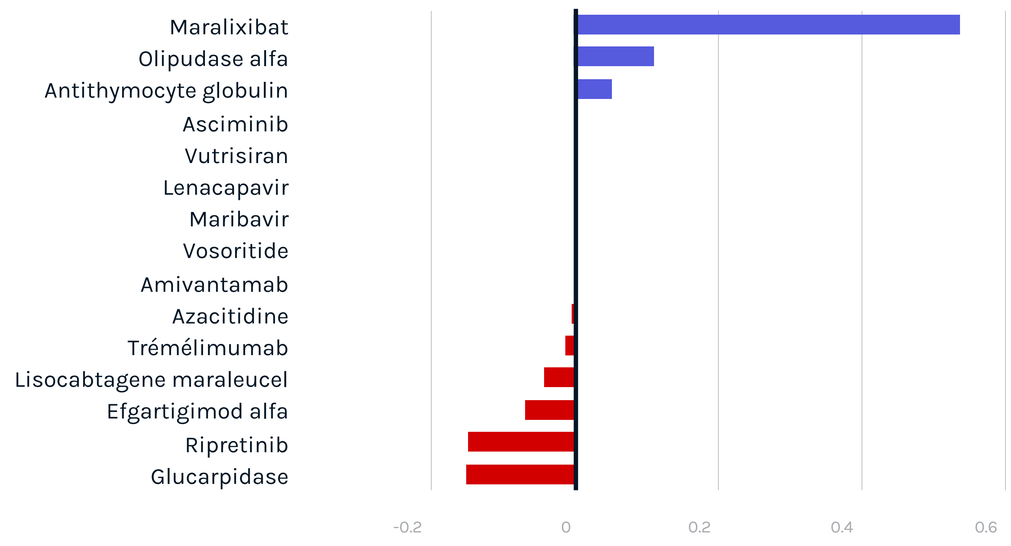
Median time from AAP start to reimbursement was 158 days (range 49 –662 days) as shown in **Figure 1**.

Figure 1. Time (in days) from AAP approval to full reimbursement



As shown in **Figure 2**, median percentage change in AAP list price to launch list price was 0% (range -15% to +54%). List prices remained unchanged for 40% (n=6) of the products, increased for 27% (n=4) and decreased for 33% (n=5). The percentage increase in price ranged from 5% to 54% relative to the original AAP price, while the decrease ranged from 1% to 15%.

Figure 2. Percentage change between AAP price and launch price



4 CONCLUSIONS

French early access programmes typically limit use to narrower, high-need populations. Most therapies launched with the same indication and no price change, demonstrating the importance for manufacturers to consider European pricing strategies early in the access pathway. Notably, changes in the target population between early access and reimbursement did not correlate with price variation, suggesting that pricing outcomes are influenced more by clinical value assessments and therapeutic context than by population scope. These patterns offer important insights for manufacturers planning launch and pricing strategies, particularly in high-priority areas like oncology and orphan diseases.

5 REFERENCES

GlobalData. Drug Pricing (POLI) & HTA Database. 2025. https://poli.globaldata.com/PricingData/Search

HAS Haute Autorité de Santé. 2025. https://www.has-sante.fr

Comité économique des produits de santé – CEPS. Autorisations d'accès précoce (ex-ATU) : montants des indemnités maximales. 2025. https://sante.gouv.fr/ministere/acteurs/instances-rattachees/comite-economique-des-produits-de-sante-ceps/article/autorisations-d-acces-precoce-ex-atu-montants-des-indemnites-maximales

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