

PROGRESSION FREE SURVIVAL AND DURATION OF TREATMENT AS A PROXY OF DISEASE SEVERITY: USE OF THESE VARIABLES TO DETERMINE PRICE BENCHMARKS

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BACKGROUND AND OBJECTIVE

In recent years, the price of oncology drugs has risen worldwide and establishing their economic value is becoming a critical issue for many NHS⁽¹⁾. In this context, the reimbursement decisions should be based on variables and endpoints that may accurately predict clinically meaningful outcomes^(1,2).

In order to evaluate the role of disease severity in the reimbursement decision-making process in Italy and if it is possible to use it to determine price benchmarks, **the main objective of this study was to compare the treatment cost of drugs indicated for solid tumors and reimbursed by the Italian NHS, based on the duration of treatment (DoT) and progression-free survival (PFS), as a proxy of disease severity.**

MATERIALS AND METHODS

A database was developed and populated with 109 AIFA-reimbursed indications for solid tumors. Drugs included in the sample had the last indication reimbursed after 2017 and eventual previous ones after 2010. The treatment cost (calculated from Ex-factory and tender price) based on DoT was calculated for each indication. The treatment cost was then divided by the months of PFS recorded in the respective clinical trials to

obtain a cost per month of PFS, interpreted as the value AIFA gave to that drug. To cluster the analysis and compare the data, **PFS and DoT were assumed as a proxy of disease severity.** Two different analyses were performed considering 4 ranges of DoT and PFS (0-3, 4-6, 7-10 and >10 months), for each analysis both Ex-factory price and tender price were applied.

RESULTS

Data collected in the database suggest that PFS and DoT can be used as a proxy for disease severity, regardless of tumor type: PFS value decrease as increase the treatment line and, therefore, the disease severity (**Figure 1**).

For the cost-therapy analysis, 34 drugs covering 71 indications were included. Using Ex-factory price, the average treatment cost per month of PFS ranges from € 8,762 considering drugs with a DoT of 0-3 months, to € 4,549 for drugs with DoT >10 months (**Figure 2**); the average treatment cost per month of PFS ranges from € 8,865 considering drugs with a PFS of 0-3 months, to € 3,974 for drugs with PFS >10 months (**Figure 3**).

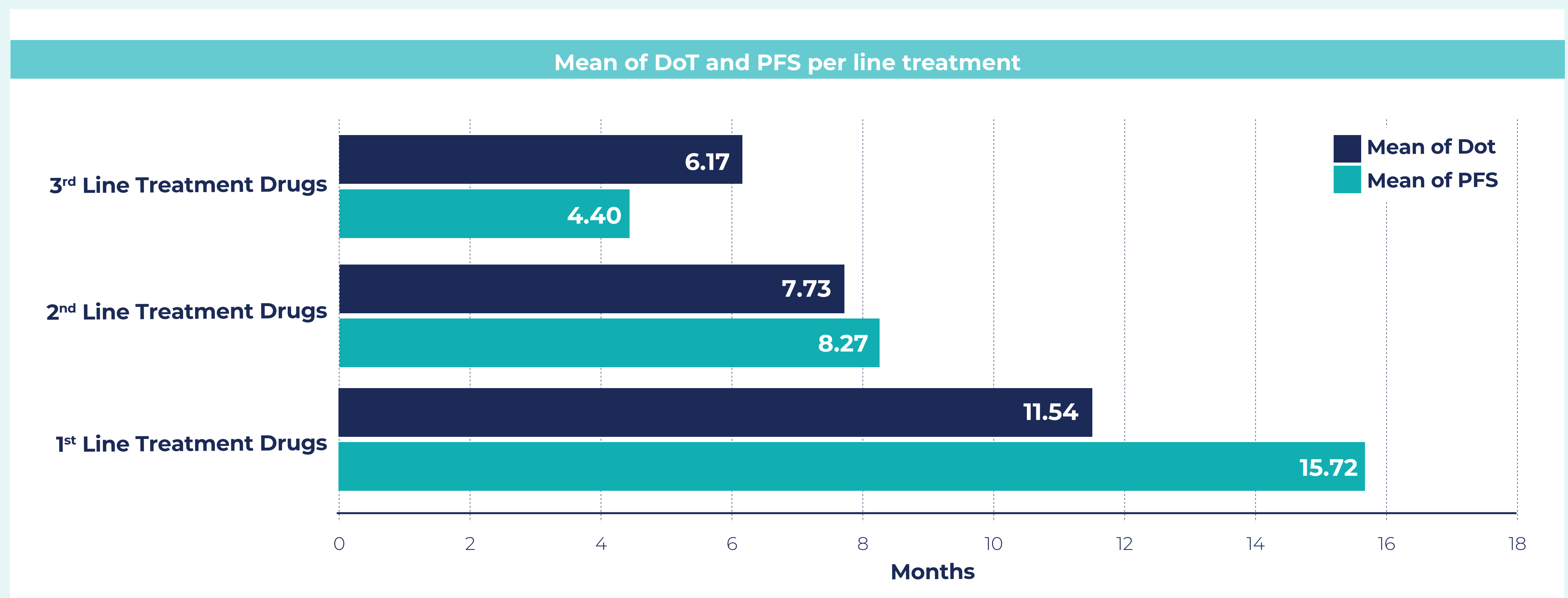


Figure 1. Correlation between PFS - DoT value and line of treatment.

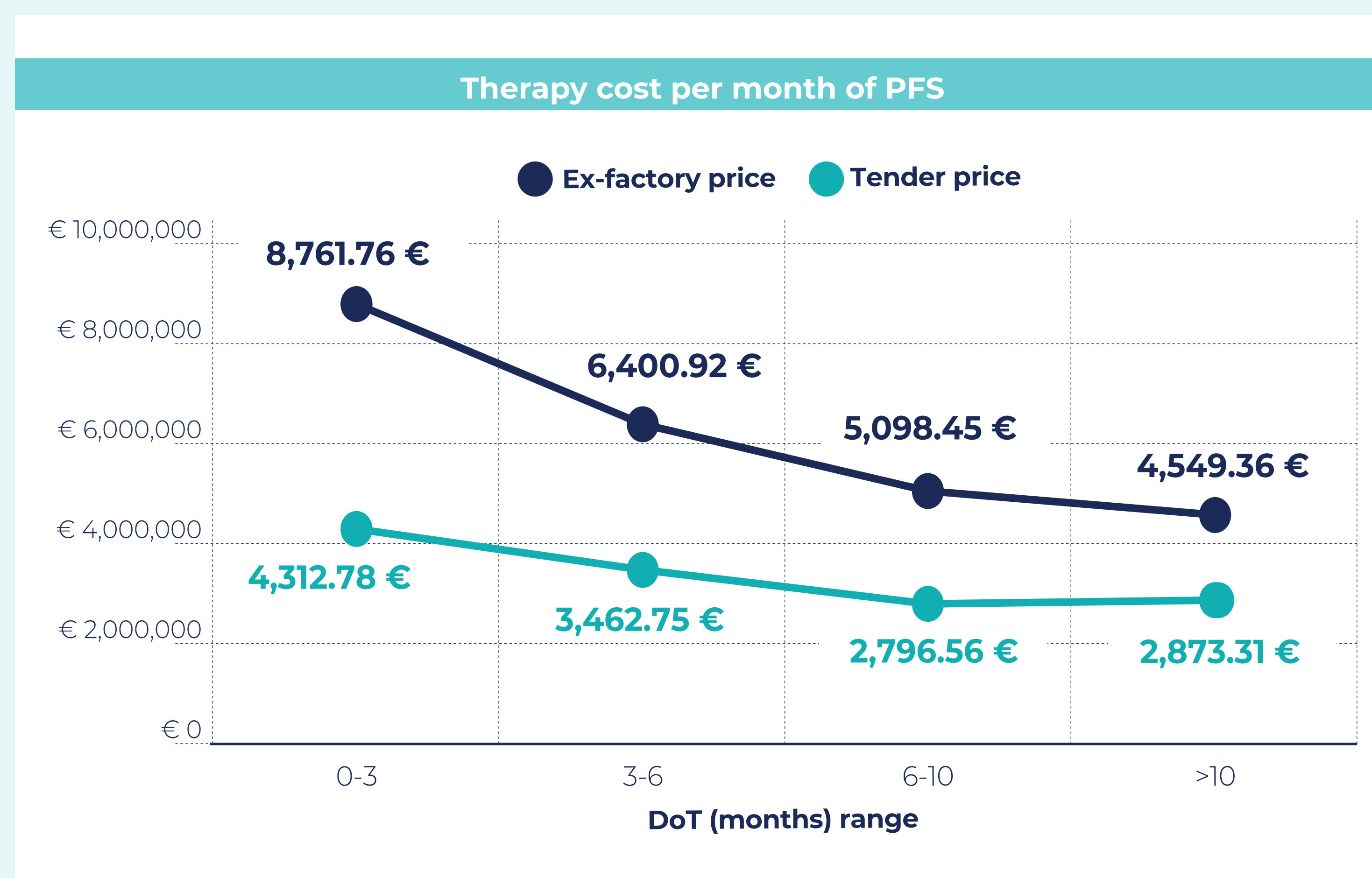


Figure 2. Therapy cost per month of PFS within DoT range (months).

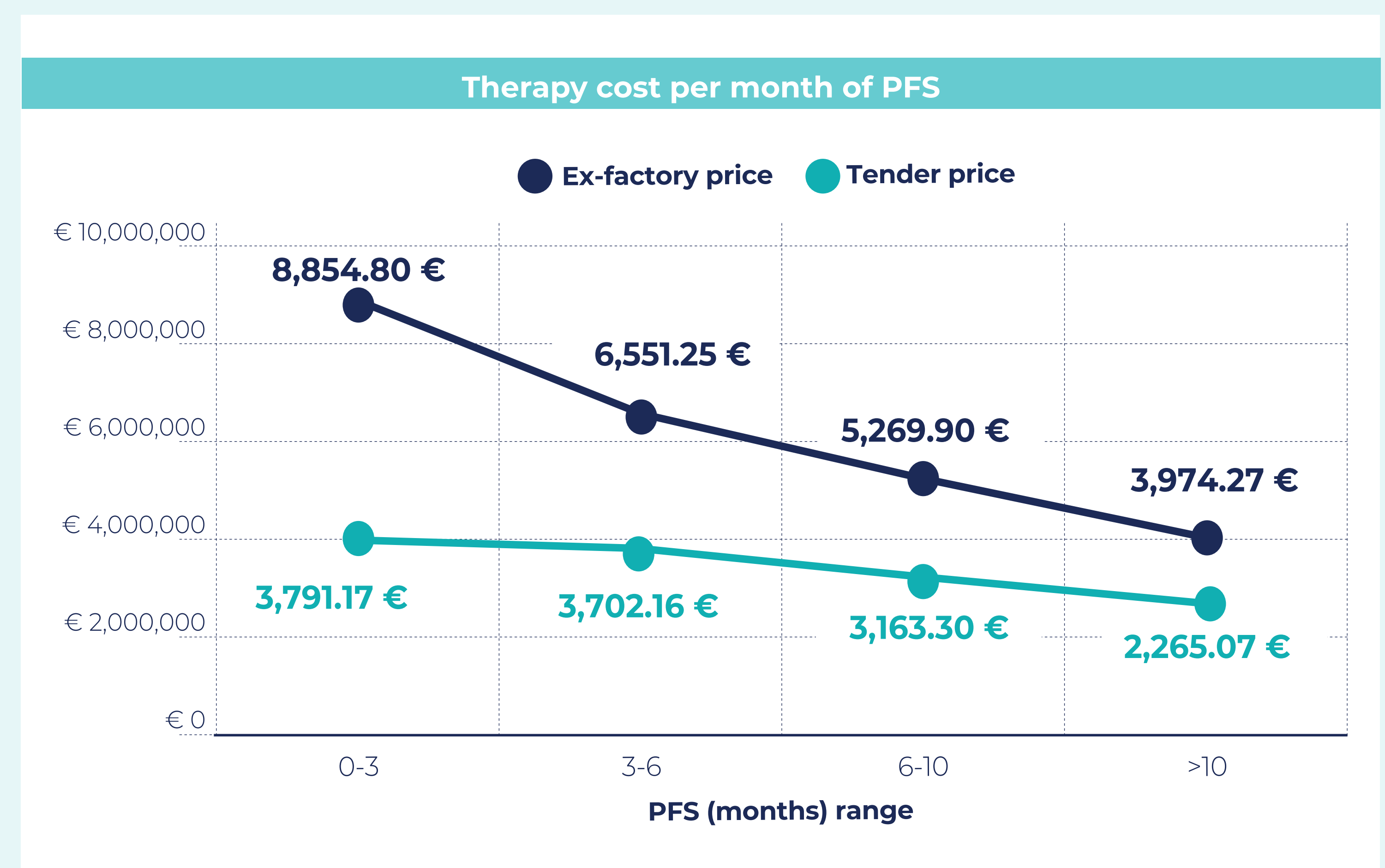


Figure 3. Therapy cost per month of PFS within PFS range (months).

CONCLUSIONS

The results of this study confirm the correlation between PFS/DoT values and line of treatment, hence disease severity. Moreover, the analysis performed showed that the economic value per month of PFS the Italian NHS assigns to these drugs, increases as DoT/PFS values decrease, thus confirming the starting assumption. These variables are therefore informative in determining the benchmark price, even without considering unmet need and added value.