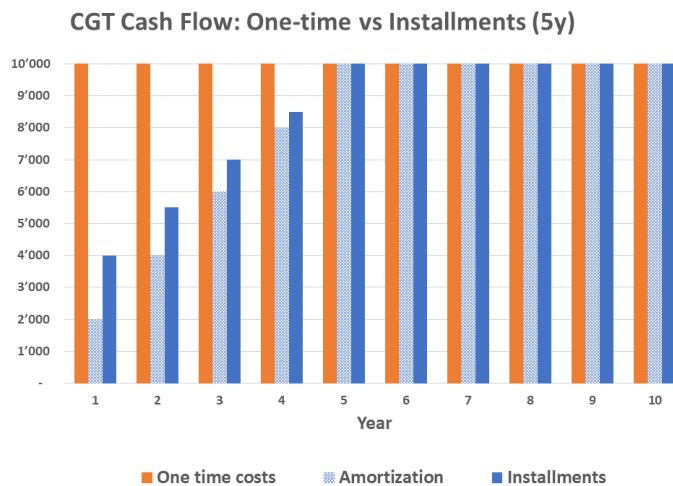


Innovative funding to reduce Budget Impact for high-cost interventions?



Kurt R. Mueller

Optimizing Market Access by bridging & aligning life science expectations with payers & decision-makers requirements & needs

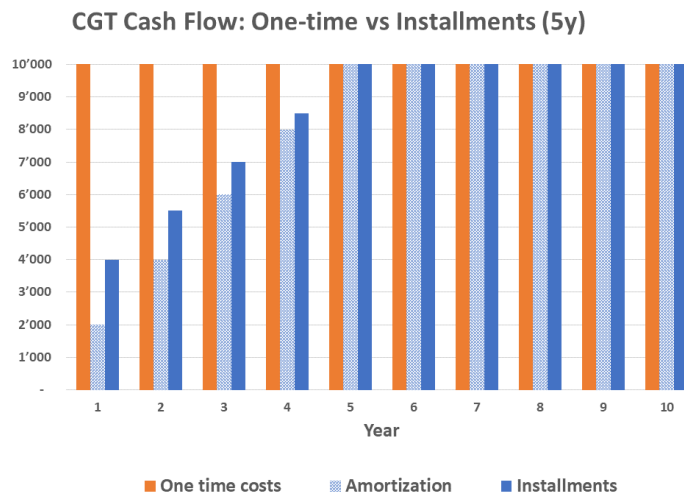
This newsletter deals with the question of whether the budget impact of cost-intensive health interventions can be positively modified by innovative financing and payment approaches.

Background

Breakthrough, cost-effective innovations to treat hepatitis C (HCV) raised concerns and fueled discussion about budget impact and affordability. Consequently, ideas of new financing models, including leasing emerged. Today, budget impact is one of payers' key concern to assess and implement innovations. Innovative funding and payment approaches are especially necessary for Cell- and Gene-Therapy (CGTs). In contrast to HCV, the level of CGTs efficacy has a broad range and many more CGTs will follow over time which makes e.g., leasing models less feasible (value uncertainty). In the following, installment payments and amortization are examined in more detail cf. [1] [\[i\]](#) [\[ii\]](#)

Cumulative Budget Impact with installment payment

In a fictitious example, the total cost of a new CGT is 1,000; 400 are paid by the payer immediately after application and in years 2-5 installments of 150 are made. There are 10 new CGTs per year and the observation horizon is 10 years.



The figure above shows that a plateau occurs after five years, and installment payments have no further influence on cash flow. This means that the payer has improved its cash flow in the first four years in its balance sheet whereas its budget impact remains unaffected (full costs must be recorded as an expense in the year of application). For comparison, amortization is shown in hatched bars, which is discussed below.

Installment payments have a positive effect on cash flow, but only for a limited period, depending on the number of new products and the length of the payment period. Installment payments do not change or modify budget impact of a new product.

Amortization

Theoretically, cell and CGTs can be capitalized and amortized as intangible goods over time. In this case, the full CGTs costs are repaid in the income statement by annual amortization contributions as expenses. A positive effect on budget impact can be seen in the first four years in this example as the income statement (profit & loss) is affected. Again, a difference versus one-time payment can only be seen in the first four years (like figure; example with 5 years linear amortization).

Amortization lowers budget impact for a limited time period, depending on the number of new products and the length of the amortization period. The use of amortization of CGTs is disputable based on current accounting standards.

Driven by Accounting Standards

Different accounting standards are used across different countries and industries (e.g., IFRS, ESA). From an accounting point of view, the full costs must be recorded as an expense in the year of application (burden on the annual budget)^[9]. The installment payment only has an impact on the cash flow. However, provisions must be booked for the remaining debt. To be able to capitalize a therapy in the balance sheet of a payer, new specific sets of rules would have to be created in accounting.

New accounting standards are to be developed for high-cost one-time therapies as CGTs

^[9] Among other things future economic benefits and transferability after application are some key issues which make capitalization as an intangible good disputable.

Performance/Outcome based Agreements

For compliance reasons, the payer should, after application of the CGT, record the full costs as a partial payment with provision for the remaining debt. If CGT does not achieve the agreed outcome, the provisions may be released - at least partially. By doing so budget impact can be reduced. Cash flow can be optimized for both payer and manufacturer by fair mutual agreements.

Payers can reduce cumulated budget impact by outcome-based agreements

Conclusion

The installment payment has a positive but temporary effect on the cash flow, but not on the budget impact. The duration of the positive cash flow effect depends on the number of new high-cost therapies a year and the time horizon for installments. Whether amortization can be used for CGTs is disputable in respect to current accounting standards. Accounting standards play a crucial role and in the event of non-compliance, tax issues are consequently to be expected. In the current situation, optimized performance-based financing seems to be the most promising way.

Limitation

The aim of this newsletter is first to explain the cumulative budget effect for installment payment and amortization using a fictitious example and second to question feasibility due to accounting regulations. Completeness and correctness are not claimed; Additions, corrections and comments are welcome.

References

1. Hanna E, Toumi M. Gene and Cell Therapies: Market Access and Funding. First Edit. Boca Raton FL: CRC Press; 2020.1-145 .

[i] Dabbous M. et al. 2021. The Amortization of Funding Gene Therapies: Making the “Intangibles” Tangible for Patients. <https://www.medrxiv.org/content/10.1101/2021.04.16.21255597v1.full>

[ii] <https://healthpayerintelligence.com/features/top-payer-strategies-around-payment-models-for-advanced-therapies>