Mapping of reimbursement rejections in Sweden using the Nordic Market Access database NMAi

HTA252

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Objective

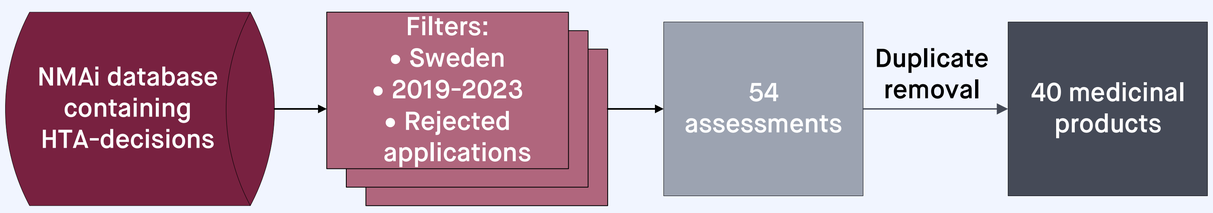
The objective of this study was to assess the most common reasons for rejection of reimbursement by the Swedish Dental and Pharmaceutical Benefits Agency (TLV)[1] during the last five years and to look for trends among these rejections in terms of disease severity, disease area, and age of the indicated population (children/adults).

Methods

All TLV reimbursement rejections published during the years 2019 to 2023 were identified by the Nordic Market Access proprietary database NMAi, using built-in filters. The NMAi tool is an automatically updated database consisting of over 10,000 documents from the year 2000 and onwards, published by the HTA bodies in Sweden, Norway and Denmark. The tool allows for filtered searches by time period, country, language, category, subcategory, and medicine. All documents are stored in the same database and can be automatically downloaded without redirecting the user to the HTA agency website.

Results

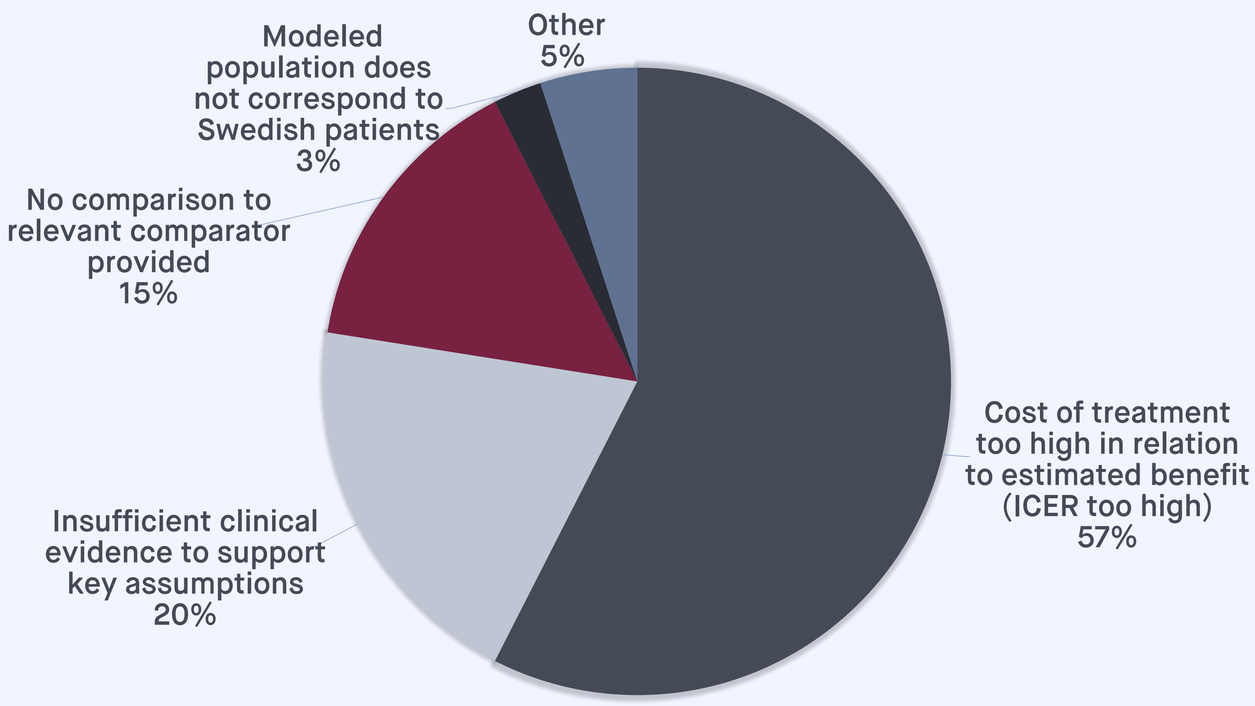
Figure 1. Selection process



A total of 54 TLV rejections concerning 40 medicinal products between January 2019 and December 2023 were identified and reviewed.

The most common primary reason for rejection was that the cost of treatment was too high in relation to the estimated clinical benefit, in other words the ICER being too high, followed by insufficient clinical evidence to support key assumptions. The third most common reason was that no comparison had been provided against the comparator that TLV deemed as most relevant, and the fourth that the study population did not correspond to the patient population intended for treatment in Sweden; see Figure 2.

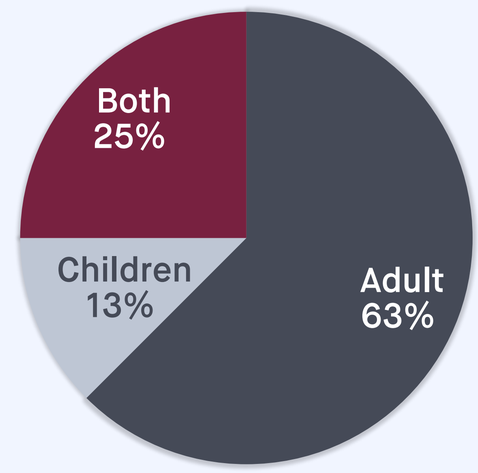
Figure 2. Primary reason for rejection



The majority of the rejections were of medications intended for adults. Only five (13%) of the rejected drugs was intended for children only (Figure 3). It was not possible to distinguish a pattern regarding disease area.

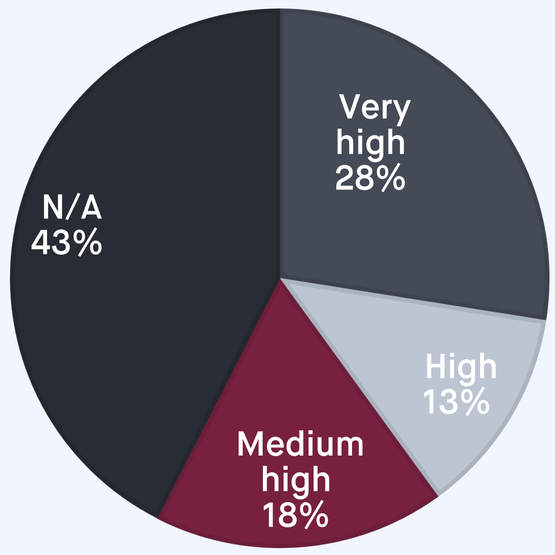
In some cases, more than one reason for rejection was given. Especially common was the combination of "ICER too high" and "insufficient clinical evidence": in 40% of the cases when the primary reason was "ICER too high", the secondary reason was "insufficient clinical evidence", and in 50% of the cases when the primary reason was "insufficient clinical evidence", the secondary reason was "ICER too high".

Figure 3. Intended population (children/adults)



The severity of the disease for the assessed indications range from very high to medium high; no indication was considered as moderate or low severity. Notably, the severity was only assessed in 57% of the cases – in 43% the disease severity was not assessed. In several of those cases, although not all, TLV state that the ICER is too high even for the highest level of disease severity.

Figure 4. Severity of disease according to TLV



Discussion & Conclusion

The results presented here indicate that the most common reason for rejection by the Swedish HTA agency TLV is that the cost of treatment is too high in relation to the estimated clinical benefit, often in combination with lack of sufficient clinical evidence to support key assumptions in the cost-effectiveness models.

The result, that the main reason for rejection is the ICER being too high, mirrors the fact that the Swedish HTA system is based on cost-effectiveness.

A continuation of this study could be to compare reasons for rejection in the other Nordic countries.

References

1. [1]Tandvårds- och läkemedelsförmånsverket, TLV. Access at www.tlv.se/.