

Outpatient Medicine Reimbursement in Sweden: An Analysis of TLV Decisions between 2016 and 2022

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Objectives

- The Swedish Dental and Pharmaceutical Benefits Agency (TLV) decides on the reimbursement of outpatient drugs
- The products evaluated by TLV are diverse and different methods are used to assess their cost effectiveness
- Objective: to describe the decisions made by TLV up to 2016

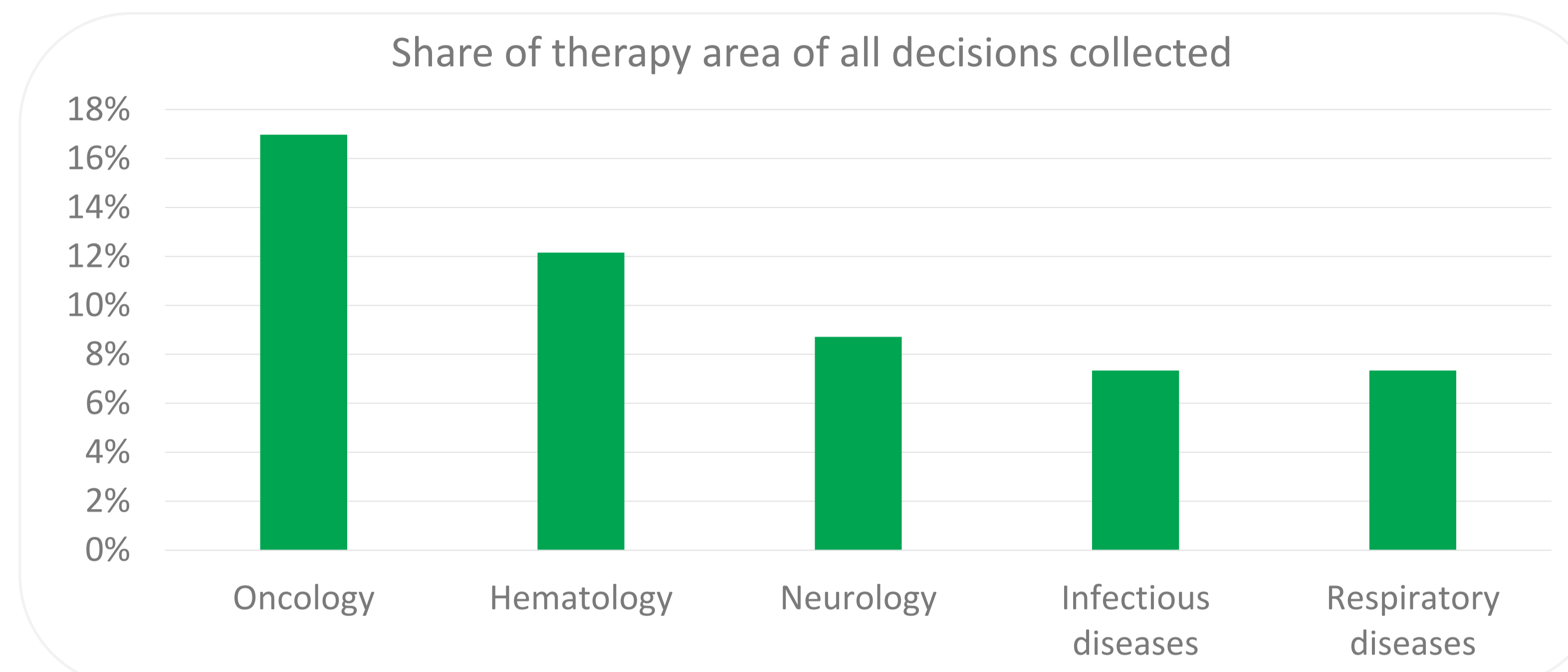
Methods

- Data from each decision made by TLV between January 2016 and June 2022 was collected
- Variables extracted:
 - Product-specific information: product name, substance name, manufacturer name, indication, whether it was a combination treatment (including add-on therapies)
 - Severity (level, range or not reported): Severity levels were recorded for products that were evaluated using cost effectiveness evaluation (when a range of severity levels was available, the lowest one was selected)
 - Decision date
 - Method used for assessing cost effectiveness: price comparison, cost comparison, cost effectiveness or multiple (if more than 1 was used)
 - Whether product was an orphan drug, a stock preparation, a generic or a biosimilar
 - Whether the product was already reimbursed for other indications
 - Use of confidential price in the evaluation
 - Reimbursement outcome for the product
- Therapy area was derived from the indications extracted

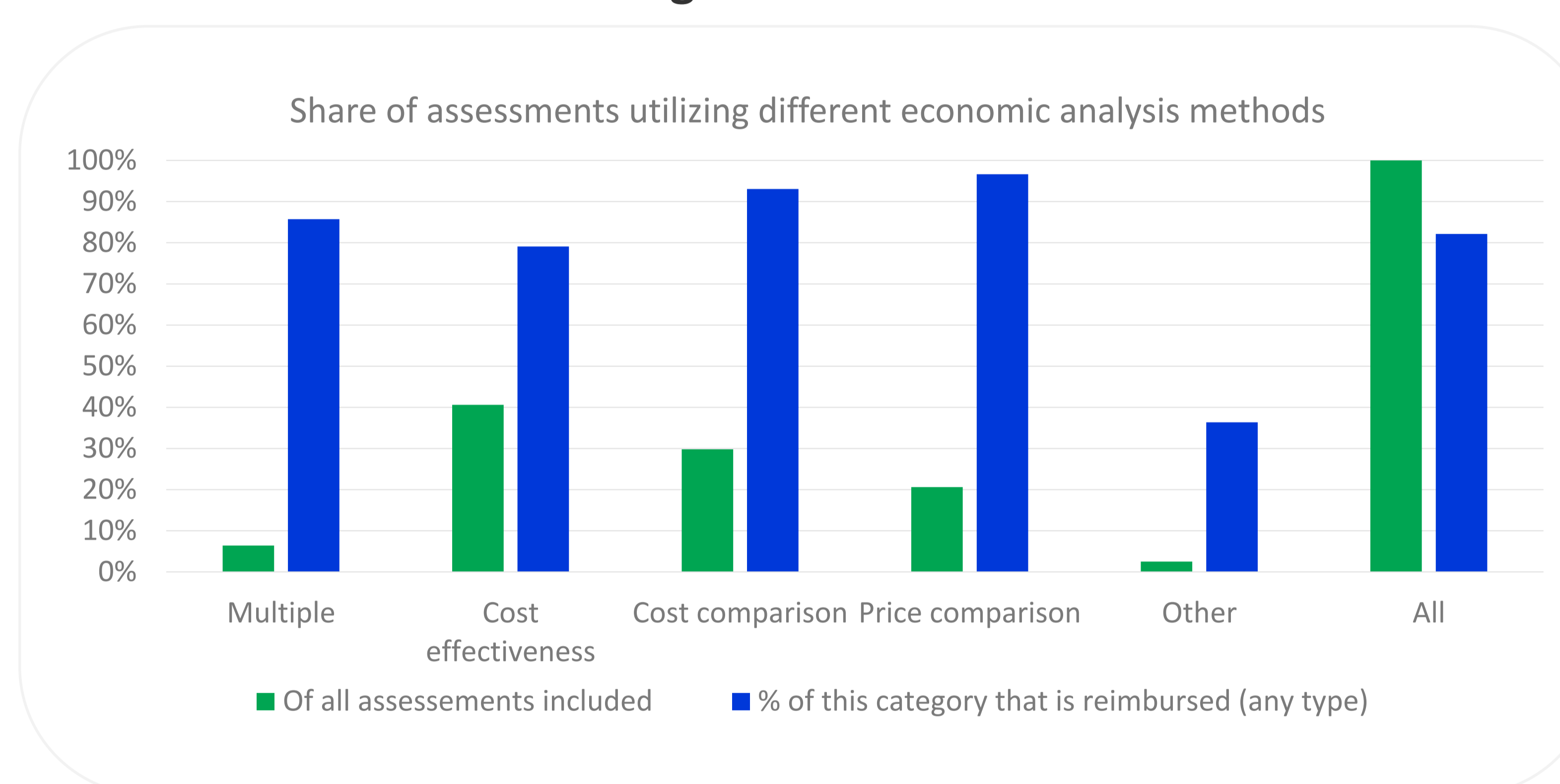
Results

- 459 decisions identified with different outcomes
 - Reimbursement: 40% general subsidy, 42% limited subsidy and 18% declined
 - Severity: 61% of decisions provide information on severity (79% severity level, 21% severity range)
 - Reimbursement status for other indications: 23% already reimbursed, 4% reimbursed in a different formulation and 73% not reimbursed
 - Combination: 14% combination treatments (including with standard of care) with 35% of these being oncology treatments
 - Confidential price agreements: used in 22% of decisions (principally for limited reimbursement [68%]). 5% of the decisions with confidential price agreements mention risk sharing
 - Product types:
 - 3% of products were orphan drugs
 - 1% of products were generics
 - 5 products were biosimilars

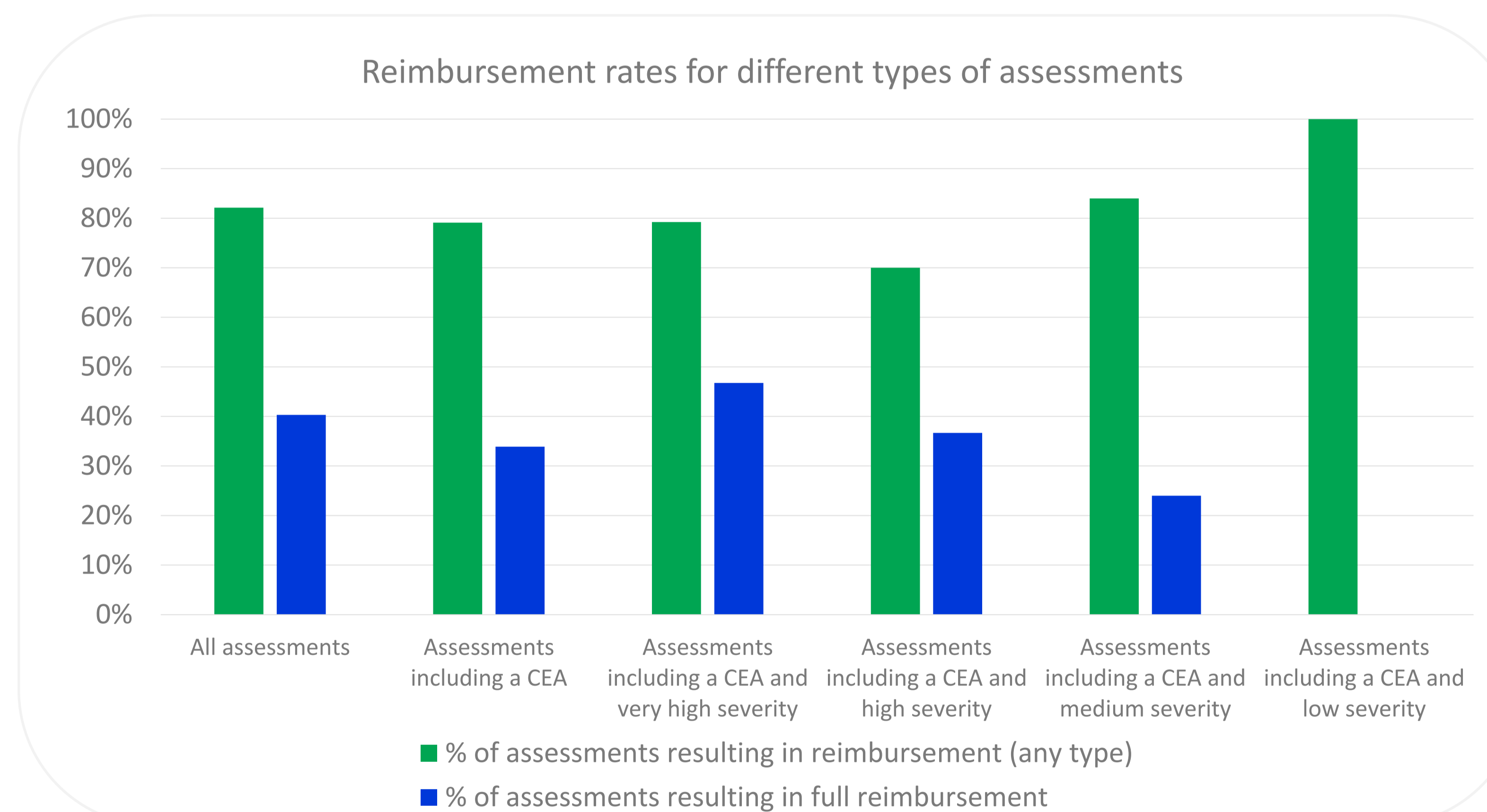
Oncology was the therapy area most assessed



Simple economic analyses (price and cost comparisons) were the most common type carried out and had the highest reimbursement rates



Reimbursement rates were similar across severities, where available



Conclusions

- Majority of TLV decisions for outpatient products in Sweden result in full or restricted reimbursement
- However, it is common that applications are withdrawn ahead of a negative decision
- Nonetheless, a greater than average rejection rate is observed when cost-effectiveness evaluations are used or indications are high severity