PND43

Budget impact of the introduction of alemtuzumab in Norway; a real world evidence analysis using data from the Norwegian Patient Registry, the Norwegian Prescription Database, and IMS sales data.

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OBJECTIVE

- To utilize real-world data (RWD) to estimate the savings for the health care sector in Norway from 2013-2018, after the introduction of alemtuzumab in 2013, and to predict the future budget impact of alemtuzumab for 2019-2027.

CONCLUSIONS

- The real world analysis, utilizing IMS sales data or combining data from NPR and NorPD, indicates that access to alemtuzumab in Norway results in cost savings.
- Due to limited health care budget, it is important to identify costs and savings in order to supply optimal health care services for patients.

INTRODUCTION

- Treatment with alemtuzumab for patients with relapsing-remitting multiple sclerosis was introduced in Norway in 2013.
- Alemtuzumab is given as 2 initial treatment courses where the second treatment course is given 12 months after the first one. Two additional treatment courses may be given if needed, with at least 12 months apart.
- Before the introduction of alemtuzumab the most commonly used treatment options for highly active MS were continuous treatment with fingolimod or natalizumab.
- Current treatment options for patients with highly active MS in Norway are alemtuzumab, ocrelizumab, fingolimod, natalizumab, and cladribine.
- Alemtuzumab provides efficacy in the absence of continuous treatment, which is assumed to generate long-term savings for the Norwegian Healthcare when compared to other disease-modifying therapies.

METHODS

- A budget impact model (BIM) was developed using RWD retrieved from the Norwegian Patient Registry (NPR), the Norwegian Prescription Database (NorPD), and Information Medical Statistics (IMS) sales data.
- The BIM was run with two scenarios; one where the patient population was based on NPR and NorPD data, and one where the patient population was based on IMS sales data.
- In 2013, the total number of patients on highly active therapy from the NPR/NorPD and IMS datasets, were 1,629 and 1,422, respectively. In 2018, the corresponding numbers from the NorPD/NPR and IMS datasets were 3,170 and 2,999, respectively. The data retrieved from all databases contained data from 2013-2018.
- After 2018, the total number of patients were extrapolated based on projected population growth retrieved from Statistics Norway.
- The model compared the current clinical practice with alemtuzumab, ocrelizumab, fingolimod, natalizumab, and cladribine, to a scenario without alemtuzumab.
- Norwegian costs for drug treatment and monitoring were retrieved from national tariffs and healthcare services.
- Re-treatment cost for alemtuzumab patients were based on calculated re-treatment rates from the NPR-data, in the period 2013-2018.
- Costs related to thyroid disorders in patients treated with alemtuzumab were also incorporated.
- The impact of alternative model settings and inputs was evaluated through sensitivity analyses.

Key assumptions and limitations

- Costs are calculated based on public list-prices, and not the confidential price approved by the Norwegian authorities.
- It is assumed that EDSS-stage is equal for all patients.
- 50% of alemtuzumab patients are assumed to have no need for additional treatment during the course of 8 years.
- Adverse events are not included in the analyses except for thyroid disorders in patients treated with alemtuzumab.

RESULTS

NPR and NorPD dataset scenario

- Due to the nature of the treatment regimen (two courses followed by durable efficacy in absence of treatment), cost savings were first seen in 2017.
- Based on our calculations, total savings from launch in 2013 to 2018 were NOK 61,942,947.
- With continued use of alemtuzumab, the savings in 2027 alone is estimated to be NOK 78,095,681, with an average yearly saving of NOK 74,593,198 from 2019-2027.
- The total savings from 2013 to 2027 is estimated to be NOK 733,281,726.

Figure 1: Calculated total costs 2013-2018, NPR and NorPD data scenario

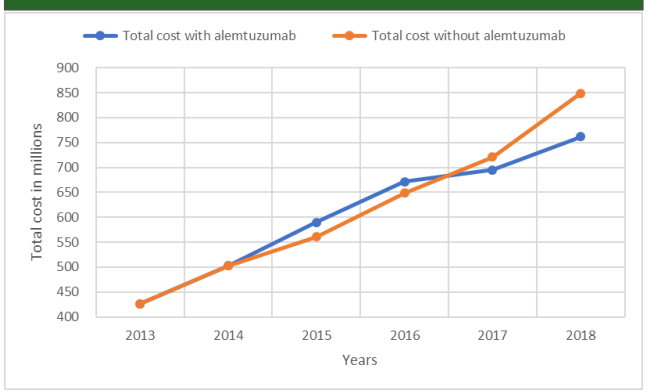
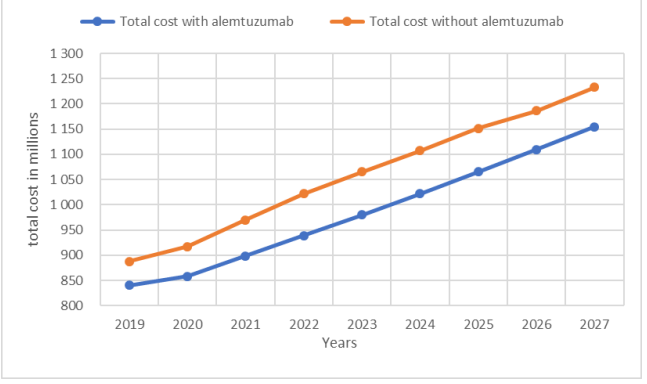


Figure 2: Estimated total costs 2019-2027, NPR and NorPD data scenario



- The two first years on alemtuzumab treatment will yield higher cost. The savings will first be seen when patients demonstrate treatment effect of alemtuzumab, in the absence of continuous treatment.
- The graph in figure 1 illustrates savings of NOK 26,347,091 in 2017 and savings of NOK 86,994,187 in 2018.
- From 2019, total cost increases both in a scenario with and without alemtuzumab due to change in patient population and market landscape.
- Annual savings are relatively stable from 2019, with NOK -86,022,966 in 2025 as the peak and NOK 46,648,181 in 2019 as the lowest (figure 2).

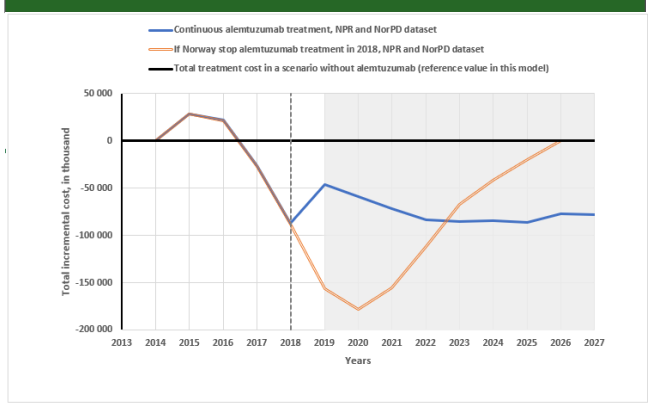
IMS-dataset scenario

- The IMS-dataset shows similar results as the NPR and NorPD dataset scenario. However, more patients were registered users of alemtuzumab in 2013 and 2014 in the IMS-dataset (8 and 68 in IMS and 0 and 2 in the NPR/NorPD), leading to higher savings in 2017.
- Based on our calculations, total savings from launch in 2013 to 2018 were NOK 78,985,972.
- With continued use of alemtuzumab, the savings in 2027 alone is estimated to be NOK 71,818,901, with an average yearly saving of NOK 72,425,226 from 2019-2027.
- The total savings from 2013 to 2027 is estimated to be NOK 730,813,002.

Estimated savings

- Figure 3 displays two scenarios with total savings between treatment with and without alemtuzumab, based on the NPR and NorPD data.
- The blue line shows savings with continuous alemtuzumab treatment, while the orange line displays savings if Norway stops alemtuzumab treatment in 2018, based on the NPR and NorPD data.

Figure 3: Estimated savings 2013-2027, NPR and NorPD data scenario



- A dotted line is added to figure 3, to emphasize the point of difference between the two scenarios.
- The shaded area display the changes in patient population and market shares due to introduction of new treatment options on the Norwegian market.
- Both datasets show total savings in the scenario analysis of ending alemtuzumab treatment in 2018, but potential savings are higher with continuous alemtuzumab treatment up to 2027.
- Comparing the total savings based on the two datasets shows similar results.

References

1. The Norwegian Medical Association, List of reimbursement codes (Normaltariffen). 2019.
2. The Norwegian Medicines Agency, Unit cost database (Enhetskostnadsdatabase). 2018.
3. Statistics Norway, Befolkningsframskrivinger. 2019.
4. The Norwegian Medicines Agency, NoMA medicine database («legemiddelsøk»). 2019.
5. Unilabs, Price list 2018: p. (Prisliste selvbetalende pasienter, Unilabs Røntgen Majorstuen).
6. The Norwegian Directorate of Health, Performance-based financing (Innsatsstyrt finansiering (ISF) – regelverk). 2019.
7. Sykehusinnkjøp HF, LIS 1805 MS ANBEFALINGER. 2018.
8. Fürst Medical Laboratory, Pricelist Norway. 2018.
9. Kappos, L., et al., A placebo-controlled trial of oral fingolimod in relapsing multiple sclerosis. N Engl J Med, 2010. 362(5): p. 387-401.
10. Polman, C.H., et al., A randomized, placebo-controlled trial of natalizumab for relapsing multiple sclerosis. N Engl J Med, 2006. 354(9): p. 899-910.
11. WHO Collaborating Centre for Drug Statistics Methodology, ATC/DDD Index. 2018.
12. Felleskatalogen, SPC Mavenclad. 2019.
13. Felleskatalogen, SPC Tysabri. 2019.
14. Felleskatalogen, SPC Ocrevus. 2019.
15. Felleskatalogen, SPC Gilenya. 2019.
16. Lovdata, Forskrift om godtgjørelse for å yte poliklinisk helsehjelp i spesialisthelsetjenesten (poliklinikkforskriften). 2019.
17. Riise, A.M.D. Bruk av interferon baserte blodtester for å påvise tuberkulosesmitte. 2007
18. Felleskatalogen, SPC Lemtrada. 2019.
19. Singer, B.A., et al., Improved Clinical and MRI Disease Activity Outcomes, Including Slowing of Brain Volume Loss, in Alemtuzumab-Treated RRMS Patients: 8-Year Follow-up of CARE-MS II (TOPAZ Study)(P3. 2-058). 2019, AAN Enterprises.
20. Comi, G., et al. Alemtuzumab improves clinical and MRI disease activity outcomes, including slowing of brain volume loss, in RRMS patients over 8 years: CARE-MS I follow-up (TOPAZ study). 2018.

Acknowledgments and Disclousures

This research was initiated and funded by Sanofi. The work and analysis are performed by LINK Medical. We are grateful for the contributions from Ingrid Norheim on treatment of thyroid disorders related to alemtuzumab. CR, BB and YM are employees of LINK Medical, ALKH is employee of Sanofi. KMM has received unrestricted research grants to his institution and/or scientific advisory board or speakers honoraria from Almirall, Biogen, Sanofi Genzyme, Merck, Novartis, Roche and Teva; and has participated in clinical trials organized by Biogen, Merck, Novartis, and Roche

Presented at ISPOR Europe, November 2-6, 2019, Copenhagen, Denmark