# Analysis of HTA Assessments, Usage, and Reimbursement of Newly Introduced Outpatient Drugs in the Netherlands between 2017 and 2021 – A Secondary Data Analysis

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## Highlights

- Between 2017 and 2021, a total of 61 outpatient drugs were introduced in the Netherlands with a cumulative cost of €751 million.
- The majority of these drugs (N = 49, 80%) were assessed by Zorginstituut Nederland, with 25 drugs being reimbursed through Annex 1A of the reimbursement system and 24 through Annex 1B.
- Budget impact analyses were published for 16 drugs and generally overestimated the costs compared to the actual reimbursement after introduction in the Netherlands. This overestimation may have implications for price negotiations and agreements.

## Objective

To gain further insight into the approval, usage, and reimbursement of outpatient drugs introduced in the Netherlands between 2017 and 2021.

## Methods

Data on the usage and reimbursement of outpatient drugs in the Netherlands were obtained from the publicly available GIP Open Data, a national database that includes prescriptions by general practitioners and specialists. The database covers drug use since 2000 for approximately 17.1 million insured individuals in the Netherlands, representing 98% coverage. For this analysis, only drugs that were first reimbursed between 2017 and 2021 were included. Public assessment reports were obtained from Zorginstituut Nederland, the Dutch Health Technology Assessment (HTA) body and used to source the estimated usage and costs in the first three years. The analysis was conducted on June 26, 2023, and updated on October 28, 2023.

## Results

Between 2017 and 2021, a total of 61 outpatient drugs were introduced and reimbursed in the Netherlands (see Figure 1), with a cumulative cost of €751 million in this period (see Figure 2). These newly introduced drugs accounted for 7% (€231 million) of the total expenditure of over €3.2 billion spent on the reimbursement of outpatient drugs in 2021 alone. On average, 12.2 ± 2.2 outpatient drugs were first reimbursed annually, ranging from 9 in 2020 to 14 in both 2018 and 2021.

### HTA assessments

Zorginstituut Nederland assessed the majority (49 out of 61; 80%) of these drugs. Half of the assessed drugs (25 out of 49; 51%) were reimbursed through Annex 1A of the Dutch reimbursement system, which imposes a reimbursement limit based on already reimbursed drugs. Budget impact analyses were published in 14 assessments covering 16 different drugs (16 out of 49; 33%). Newly reimbursed products without assessment mainly concerned combination products.

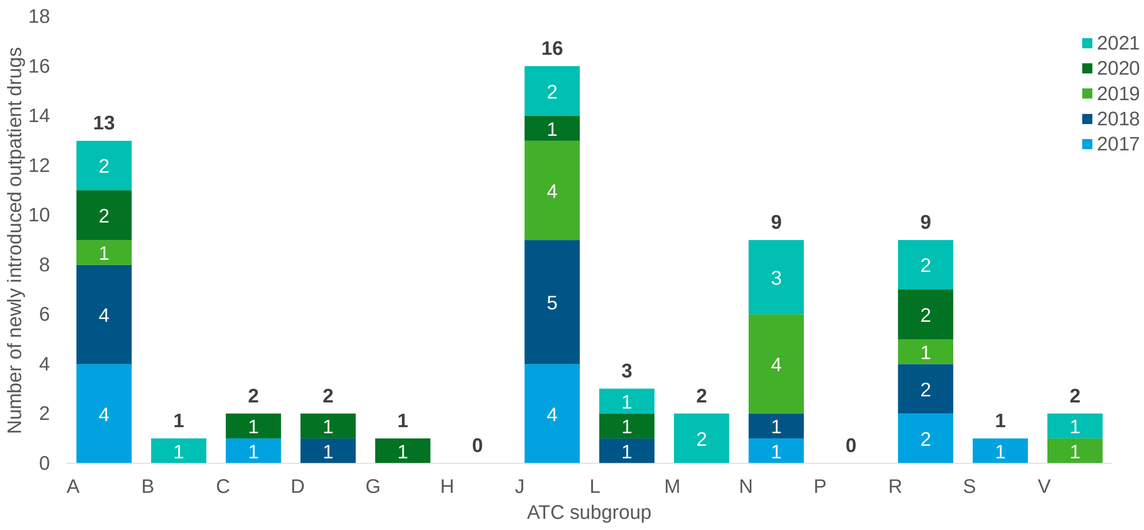


**Figure 1:** Number of newly introduced outpatient drugs between 2017 and 2021 in the Netherlands stratified per ATC category.

A – alimentary tract and metabolism, B- blood and blood forming organs, C – cardiovascular system, D – dermatologicals, G – genito urinary system and sex hormones, H – systemic hormonal preparations, excluding sex hormones and insulins, J – anti-infective for systemic use, L – antineoplastic and immunomodulating agents, M – musculo-skeletal system, N – nervous system, P – antiparasitic products, insecticides and repellents, R – respiratory system, S- sensory organs, V – various.

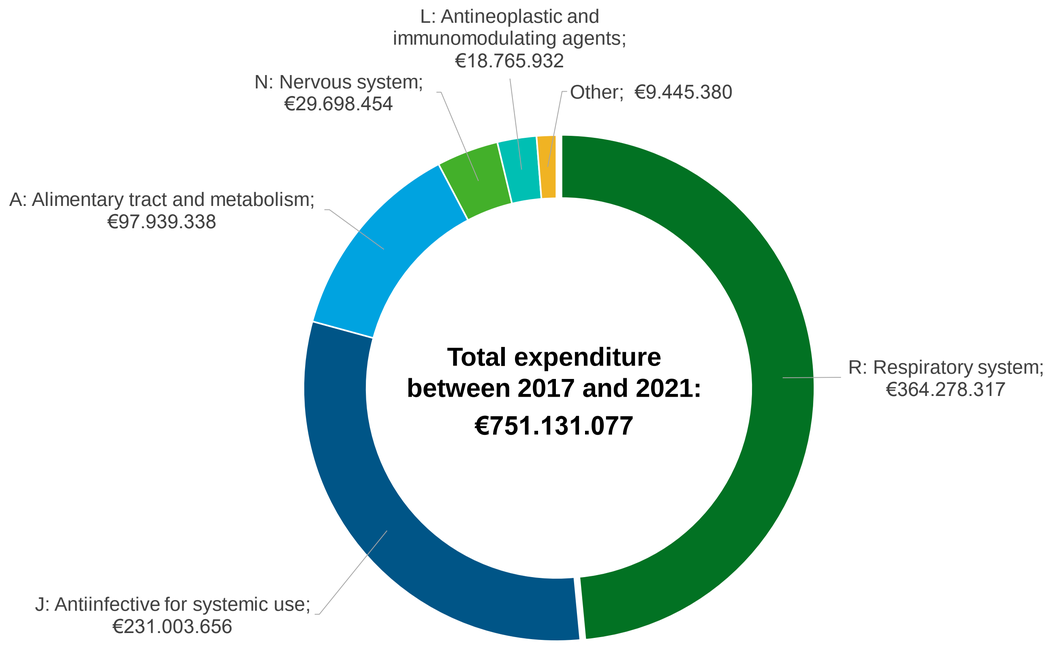


**Figure 2:** Overview of the total reimbursement between 2017 and 2021 in the Netherlands on newly introduced outpatient products in the same period, stratified per ATC category.

### Usage and reimbursement

Anti-infectives for systemic use

Of the 61 outpatient drugs introduced and reimbursed in the Netherlands between 2017 and 2021, 26% (16) belonged to ATC category J, anti-infectives for systemic use. Those drugs accounted for nearly one-third of the expenditure on reimbursements during the same period (€231 million out of €751 million; 31%). Seven products for the treatment of HIV infections were introduced, along with anti-infectives for the treatment of hepatitis C (4 products), hepatitis B (1 product), CMV (1 product), Herpes Zoster (1 product), aspergillosis (1 product), and meningitis (1 product).

Respiratory system

Nearly half (48%) of the healthcare expenditure on new outpatient drugs between 2017 and 2021 was spent on 9 drugs belonging to ATC category of the respiratory system (R). The CFTR-modulators lumacaftor/ivacaftor (Orkambi®) and tezacaftor/ivacaftor (Symkevi®) accounted for 87% of the expenditure within this category (€315 million of €364 million), and 42% of the overall expenditure.

Alimentary tract and metabolism

A total of 13 drugs were introduced between 2017 and 2021 that belonged to ATC category A. Drugs for the treatment of diabetes mellitus accounted for one-third of this group (4 out of 13; 31%), including semaglutide (Ozempic®) which was first reimbursed in 2018. The number of patients treated with semaglutide increased from 1,264 in 2018 (with an overall cost of €380,019) to 42,219 in 2021 (with an overall cost of €36.2 million). Reimbursement of semaglutide accounted for 71% of the expenditure within this category (€70 million out of €98 million), and 9% of the overall expenditure.

### Budget impact

Budget impact analyses are a mandatory element of most Annex 1B applications, which are submitted for products with a claim of added therapeutic value compared to currently available treatments. The costs of outpatient drugs were generally overestimated at the time of health technology assessment compared to the actual reimbursement (see Table 1). For example, idebenon (Raxone®) was estimated to cost €66,963 per patient per year but actually costed less than €46,300 on average per patient per year since its introduction in 2017. The expenditure was, however, also found to be higher than estimated in some cases. For instance, the estimated price per patient per year for naloxegol (Akynzeo®) was €208 whereas the actual reimbursement was nearly three times higher than estimated with an average reimbursement of €611 per patient in 2022.

**Table 1:** Overview of the estimated usage and cost as mentioned in the budget impact analysis of the HTA assessment and the actual usage and cost as reported in the GIP Open Data of selected outpatient drugs which were reimbursed via Annex 1B of the Dutch reimbursement system. The estimations are based on each 12-month period from reimbursement date, whereas the actuals are reported per calendar year. The highest estimations are used in case multiple scenarios were described in the HTA assessment.

| | | Patients | | | Budget (€) | | | |
|---|---|---|---|---|---|---|---|---|
| | | Year 1 | Year 2 | Year 3 | Year 1 | Year 2 | Year 3 | Total |
| **Palonesteron (Akynzeo®) - 2017** | Estimated | 1,970 | 2,693 | 6,633 | 397,196 | 798,384 | 1,337,294 | **2,532,874** |
| | Actual | 68 | 1,221 | 3,685 | 10,630 | 258,161 | 793,964 | **1,062,755** |
| **Naloxegol (Moventig®) - 2017** | Estimated | 914 | 1,599 | 2,056 | 190,021 | 332,432 | 427,442 | **949,895** |
| | Actual | 125 | 795 | 1,218 | 25,412 | 307,037 | 597,962 | **930,411** |
| **Idebenon (Raxone®) - 2017** | Estimated | 34 | 34 | 34 | 2,300,000 | 2,300,000 | 2,300,000 | **6,900,000** |
| | Actual | 18 | 46 | 47 | 110,593 | 1,990,907 | 1,993,723 | **4,095,223** |
| **Telotristat (Xermelo®) - 2018** | Estimated | 96 | 77 | 81 | 646,469 | 1,157,409 | 1,220,627 | **3,024,505** |
| | Actual | 12 | 39 | 39 | 28,596 | 226,893 | 307,987 | **563,476** |
| **Roflumilast (Daxas®) - 2018** | Estimated | 2,040 | 3,060 | 4,080 | 1,992,992 | 1,789,488 | 2,385,984 | **5,368,464** |
| | Actual | 64 | 451 | 539 | 7,386 | 85,040 | 174,800 | **267,222** |
| **Letermovir (Prevymis®) - 2019** | Estimated | 30 | 91 | 135 | 444,150 | 1,332,450 | 1,993,500 | **3,770,100** |
| | Actual | 17 | 54 | 94 | 380,120 | 1,051,700 | 1,833,00 | **3,264,741** |
| **Pitolisant (Wakix®) - 2019** | Estimated | 468 | 695 | 1,032 | 3,553,594 | 5,259,319 | 7,817,907 | **16,630,178** |
| | Actual | 83 | 183 | 225 | 266,469 | 1,081,412 | 1,170,052 | **2,517,933** |
| **Asfotase alfa (Stensiq®) - 2020** | Estimated | 4 | 4 | 5 | 873,596 | 1,009,844 | 1,226,239 | **-** |
| | Actual | 1 | 2 | - | 142,491 | 1,125,890 | - | **-** |
| **Trientine (Cuprior®) - 2020** | Estimated | 33 | 33 | 33 | 2,188,175 | 2,188,175 | 2,188,175 | **-** |
| | Actual | 24 | 34 | - | 519,332 | 1,529,197 | - | **-** |
| **Meningococcal Group B vaccine (Bexsero®) - 2020** | Estimated | 2,462 | 2,462 | 2,462 | 579,727 | 579,727 | 579,727 | **-** |
| | Actual | 588 | 640 | - | 68,796 | 76,021 | - | **-** |
| **Givosiran (Givlaari®) - 2021** | Estimated | 13 | 14 | 15 | 6,904,028 | 7,456,350 | 8,008,672 | **-** |
| | Actual | 4 | - | - | 288,612 | - | - | **-** |
| **Recombinant Zoster Vaccin (Shingrix®) - 2021** | Estimated | 12,213 | 12,213 | 12,213 | 4,974,760 | 4,974,760 | 4,974,760 | **-** |
| | Actual | 570 | - | - | 127,841 | - | - | **-** |
| **CGRP mAbs erenumab, galcanezumab, and fremanezumab - 2021** | Estimated | 2,866 | 2,509 | 2,986 | 12,504,078 | 12,934,609 | 15,712,899 | **-** |
| | Actual | 1,590 | - | - | 1,944,494 | - | - | **-** |

## Conclusions

This secondary data analysis of HTA assessments, usage, and reimbursement of newly introduced outpatient drugs in the Netherlands from 2017 to 2021 revealed that 61 drugs were introduced in the Netherlands during this five-year period. About half of these drugs were considered of equal therapeutic value to currently available drugs. The estimated budget impact at the time of HTA assessment tends to overestimate the actual reimbursed budget.

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