

Analysis of the substances included in itemized accounting in October 2018 — case study

Annex 1/A. to 9/1993. (IV. 2.) NM Regulation sets out the so-called itemized accounting active substances which are provided to the institutions in kind by NHIF, according to Article 2/B. § (2). A key requirement for this is NHIF carrying out a public procurement procedure for the products containing the given substances, and concluding a delivery contract with the successful tenderer. However, according to Article 2/B. § (2), NHIF is entitled to provide a financial framework to the institutions for a transitional period, so they can finance the needed quantity of medicines from it but on their own initiative. (NEAK)

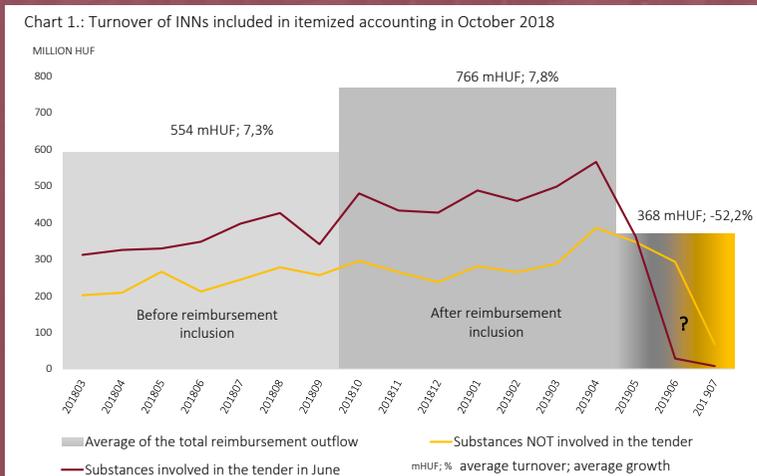
From 15th October 2018, 14 new active substances were included from itemized accounting. However, NEAK initialized the first tender procedure only on 12th June 2019, and only for a part of the newly reimbursed substances. These medicines included in the tender are expected to be provided in kind to the institutions from this fall. (EKR) From the day of reimbursement inclusion – and the enactment of the needed amendment of legislation – to the concluding of a delivery contract, there is a transitional - but in this case, not short – period. In this period, the regular financing of these products continues, on the account of Named Patient Program (NPP), so it is possible to examine their turnover since there is public data of it published by NHIF. However, if NHIF provides a financial framework to the institutions, there is

Table 1. New substances included in itemized accounting in October, 2018

New active substance	ATC	Brand	Indication (indication point)	Start date of tender	201806 - 201905 MAT reimbursement outflow HUF
<i>vedolizumab</i>	L04AA33	ENTYVIO	Crohn (1/a1;1/a2), Ulcerosa colitis (2/a)	2019.06.12	585 181 022
<i>secukinumab</i>	L04AC10	COSENTYX	Spondylitis anky. (3), Plakkos ps. (5)	2019.06.12	685 785 353
<i>ixekizumab</i>	L04AC13	TALTZ	Plakkos psoriasis (5)	2019.06.12	404 655 744
<i>baricitinib</i>	L04AA37	OLUMIANT	Rheumatoid arthritis (6/a1)	2019.06.12	149 838 000
<i>tofacitinib</i>	L04AA29	XELJANZ	Rheumatoid arthritis (6/a1)	2019.06.12	125 394 081
<i>daratumumab</i>	L01XC24	DARZALEX	Myeloma multiplex (7/a)	2019.06.12	1 168 129 830
<i>carfilzomib</i>	L01XX45	KYPROLIS	Myeloma multiplex (7/a)	2019.06.12	542 037 180
<i>atezolizumab</i>	L01XC32	TECENTRIQ	Non-small-cell lung carcinoma (8/a7)	2019.06.12	307 067 796
<i>crizotinib</i>	L01XE16	XALKORI	Non-small-cell lung carcinoma (8/a8)	2019.06.12	635 370 388
<i>alectinib</i>	L01XE36	ALECENSA	Non-small-cell lung carcinoma (8/a8)	2019.06.12	618 833 681
<i>trastuzumab emtanzine</i>	L01XC14	KADCYLA	Breast cancer (8/c3)		1 152 471 531
<i>pertuzumab</i>	L01XC13	PERJETA	Breast cancer (8/c4)		2 113 150 132
<i>cobimetinib</i>	L01XE38	COTELLIC	Melanoma (14)		
<i>trametinib</i>	L01XE25	MEKINIST	Melanoma (14)		85 699 942
Total:					8 573 614 680

no public data about their turnover. In our current case study we examine the reimbursement (NPP) turnover of the substances concerned, partly for the purpose of seeing, whether we can observe a time period when institutions already had and used a financial framework procuring these medicines. Table 1. shows the substances included in itemized accounting in October 2018, their reimbursed indications, start date of tender procedure and their MAT reimbursement (NPP) in the period 01/06/2018 – 31/05/2019. As stated in the table, currently there are four active substances which have not been included in public procurement yet, these are trastuzumab emtanzine, pertuzumab, cobimetinib and trametinib. Out of these four, only cobimetinib had no reimbursement outflow in the examined period, and trametinib's turnover was only a few package per month. But trastuzumab emtanzine and pertuzumab had excessively high turnover among the other relevant substances.

The 1. chart shows the trends of the examined substances' turnover from March 2018, in three sections. For seven months before and after the inclusion, and for the May – July 2019 period we can see the average total turnover (of the examined drugs), and the average growth of it. The chart also contains the monthly reimbursement outflow of the two groups of substances (included and not included in tender in June).



The total reimbursement turnover of the 14 substances in 2018 gave 29% of the total amount of NPP turnover. In the 7 months before the reimbursement inclusion, the average monthly reimbursement outflow of the relevant substances was 554 million HUF, which increased to 766 million HUF in the October 2018 – April 2019 period. In the first 5 months of 2019, the share of these substances in the total NPP turnover remained at 29%. In amounts, the turnover of the examined circle of active substances reached its maximum in April 2019, with 951 million HUF reimbursement outflow.

These trends lead to the conclusion that after the appearance of the amendment in the related legislation, NHIF has not been provided funding to the institutions, so the procurement of the examined drugs continued within the pharmacy drug budget, as NPP. However, after the peak in April 2019, there was a downturn in May and in June, the reimbursement turnover of the tender included drugs decreased practically to zero. This suggests that partially in May, but from June, the procurement of these drugs was fully charged to the financial framework of the institutions. Based on the public data for July 2019, the procurement of the other three drugs might have been delegated to the institutions (for cobimetinib we do not see any turnover in public data). The remaining turnover probably belongs to use of these medicines in off label or not reimbursed but registered indications. Based on public data, it is not possible to get an exact date, from when the procurement of the relevant therapies are funded only within financial framework. However, it is reasonable to state that between April and July 2019, the change in the financing technique has happened.

CONCLUSION

In October 2018 the circle of itemized accounting drugs expanded with 14 active substances, which gave till then the 29% of total NPP turnover. However, the change of financing status have not been followed by an immediate change in reimbursement.

OCTOBER 2018

- ◆ Not reimbursed status, NPP turnover
- ◆ Net reimbursement prices unknown
- ◆ NPP turnover publicly available

OCTOBER 2018—APRIL 2019

- ◆ Itemized status, NPP turnover
- ◆ No change in practice

MAY 2019

- ◆ Introduction of financial framework agreement (FFA)
- ◆ Conditions, duration of FFA is unknown
- ◆ Turnover data not available
- ◆ The practical implementation and rational usage of hospitals is questionable, due to the sudden change

JUNE 2019

- ◆ Public procurement for 10 of the 14 substances
- ◆ 4 remaining substance
- ◆ No information about the conduct of the tender

It has been 11 months, since these substances in question were published as itemized accounting substances. But the measures taken in this period did not get us closer to the final solution. It is still uncertain, when the financing situation of these substances will be satisfactory resolved.