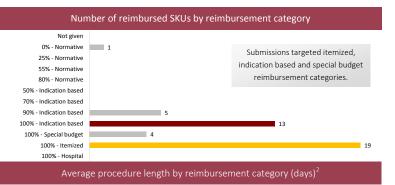
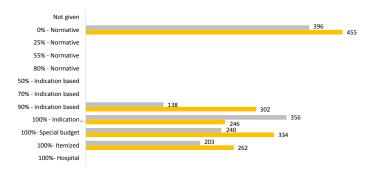


Analysis of the submission procedures of newly published products

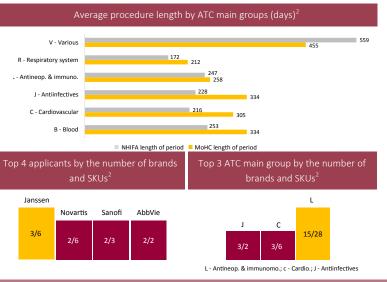
Newsletter Special edition, Issue X. 2020 Published: 29/01/2020

Since our previous <u>special edition</u>, the Analysis of the submission procedures of newly published products in October 2018, 404 submissions (125 normal and 279 simplified) got final decision by National Health Insurance Fund of Hungary (NHIFA) and Ministry of Human Capacities (MOHC). After 14 months new reimbursement categories were published in the Hungarian Gazette on December 30 2019 (entered into force on January 15 2020), including 25 brands, 16 totally new substance and 19 therapeutic areas. These products do not cover all indication areas that are waiting for reimbursement. This analysis focuses only these newly reimbursed technologies and bases on the data published by the NHIFA on January 15 2020.





NHIFA length of period MoHC length of period



During the NHIFA co-ordinated period, the financing structure for the technology has been determined on the basis of submitted and agreed HTA, BIA and medical considerations. The final decision has been taken by a Committee coordinated by the Ministry.

- The average procedure time of the newly reimbursed products is 534 days (min-max: 320 and 1014 days
- The average procedure time of NHIFA is 252 days (min-max: 93 and 605 days)
- The average procedure time of MoHC is 274 days (min-max: 212 and 536 day



Number of the reimbursed submission procedures by ATC5 codes

ATC5	Name	Brand	SKU
L01XE	Protein kinase inhibitors	3	8
L04AC	Interleukin inhibitors	4	6
C09DX	Angiotensin II receptor blockers (ARBs), other combinations	1	4
L01XX	Other antineoplastic agents	2	4
L01BB	Purine analogues	1	3
J05AP	Antivirals for treatment of HCV infections	2	2
L01XC	Monoclonal antibodies	1	2
L03AB	Interferons	1	2
N04BC	Dopamine antagonists	1	2
B02BD	Blood coagulation factors	1	1
B02BX	Other systemic hemostatics	1	1
СО2КХ	Antihypertensives for pulmonary arterial hypertension	1	1
C03DA	Aldosterone-antagonists	1	1
L01CD	Taxans	1	1
L02BB	Antiandrogens	1	1
L02BX	Other hormone antagonists and related agents	1	1
R03DX	Other systemic drugs for obstructive airway diseases	1	1
V04CJ	Tests for thyreoidea function	1	1
Total		25	42

MAT NPP (Named Patient Program) turnover by ATC5 codes

ATC5	Name	Pack tunover (201812-201911)	Reimb. turnover HUF (EUR* (201812-201911
L01XE	Protein kináz gátlók	91	141 997 645 (421 158)
L04AC	Interleukin inhibitorok	2 058	616 565 428 (1 828 703)
C09DX	Angiotensin II antagonisták, egyéb kombinációk	4 697	148 918 826 (441 686)
L01XX	Egyéb cytostati cumok		
L01BB	Purine analógok	216	476 865 235 (1 414 359)
105AP	HCV-fertőzés elleni antiviralis szerek		
L01XC	Monoclonalis antitestek		
L03AB	Interferonok	12	2 541 600 (7 538)
N04BC	Dopamine antagonisták	16	910 352 (2 700)
B02BD	Véralvadási faktorok		
B02BX	Egyéb systemás haemostaticumok		
С02КХ	Egyéb antihypertensivumok	952	258 454 785 (766 564
C03DA	Aldosteron-antagonisták	34	222 264 (659)
L01CD	Taxanok	4 449	378 604 430 (1 122 922)
LO2BB	Antiandrogenek		
LO2BX	Egyéb hormon antagonisták és rokon anyagok		
R03DX	Obstructiv légúti betegségekre ható egyéb systemás szere	2k	
V04CJ	Pajzsmirigy-működés tesztek		
Total		12 525	2 025 080 565 (6 006 289)

nalysis of published data has shown that these products already have relevant MAT NPP reimbursem rnover (2 billion HUF; 6 million EUR).

If we compare these data to previous year's, it shows that the Law on General Administrative Order, which entered into force in 2018, did not speed up the procedure time of reibursement of innovative medicines. However, it should be noted that according to public data on the NHIFA website, statistics of procedure time for medicines are better, than for new health technologies which awaiting for the amendment of the legislation.

With further questions, please contact us!

Submission		Positive preliminary	decision	Final decision & publication
•	NHIFA ¹		MoHC ¹	
	252 days on average (min-max: 93 -605 days)		274 days on average (min-max: 212 —536	days)
0. day	90. day ³	252. day		534. day
			¹ NHIFA: National Health Insurance Fund of Hungary ² Healthware analysis based on NHIFA data ³ Standard official process period of NHIFA	

in

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