Reimbursement of High Priced One-Shot Treatments in Korea: KYMRIAH and ZOLGENSMA Case Study

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BACKGROUND

With the listing of both KYMRIAH and ZOLGENSMA in 2022, the Korean government recognized a need to develop a regulatory system for the listing of high priced serious disease therapies to manage patient access and the national health insurance budget. And in this regard, the government announced their policy directive[1]. According to the government's press release, the Health Insurance Policy Review Committee (a committee organized under the Ministry of Health and Welfare) created a definition of "High Priced Drug Products" and designated the type of products that are in need of special reimbursement management.

OBJECTIVE

After the reimbursement listing of two one-shot treatments in 2022, KYMRIAH and ZOLGENSMA, the Korean government has announced policies on the listing of high priced treatments. In this study, we analyzed this newly announced policy based on a review of the KYMRIAH and ZOLGENSMA listing precedents.

METHODS

We reviewed the key policies of the reimbursement method for high priced treatments announced by the Korean government in 2022, and analyzed the P&R scheme applied to KYMRIAH and ZOLGENSMA.

RESULTS

Definition of High Priced Drugs

① Drugs that require price management and long term efficacy verification due to their high price and uncertainty in efficacy; or

② Drugs that require volume management due to substantial budget impact

Drugs Subject to Reimbursement Management

Listed products and listing application products which:

① Expect long term efficacy based on a single treatment (one-shot therapy) or has an annual treatment cost of at least KRW 300,000,000 per person (ultra-high priced new drug);

② Has an annual claim amount of at least KRW 30,000,000,000

Due to the lack of an international standard on what constitutes an "high cost" or "premium-priced" drug product, the Korean government developed its own definition as set forth above based on an analysis of claim data filed with the Health Insurance Review and Assessment Service (HIRA).

The policy directive is separated into short term (2022) and long term (2023 and beyond) policies, which introduce specific schemes based on the following three main objectives: (1) increased patient access, (2) strengthened monitoring of treatment efficacy and safety and (3) strengthened reimbursement management. KYMRIAH and ZOLGENSMA were listed by applying a combination of various schemes such as refund, performance based RSA, expenditure cap and prior approval **<Table 1>**.

Objective	Policy Directive
Increased Patient Access	Parallel implementation of reimbursement evaluation and price negotiation for life threatening disease therapies
	Introduction/operation of per patient performance based RSA
Strengthened monitoring of treatment efficacy and safety	Establish data collection system for post-listing management of high priced drugs
Strengthened reimbursement management	Establish system for prior approval of high priced drugs

Table 1. Listing Precedents of Single Treatment Therapies

Drug	Characteristics	RSA Type					Prior Approval
		Refund type (①+②)				Expenditure Cap	
		① Basic Refund	② Performance based per patient				
				Performance indicator	Data Collection		
Leukemia Therapy (listed '22.4.)							
1. Pediatric ALL	Single treatment therapy (one-shot)	○	×	-	-	○	×
2. Adult DLBCL		○	○	PFS	○*	○	×
Spinal Muscular Atrophy Therapy (listed '22.8.)		○	○	Motor Function	○**	○	○

* Total 3 data collections: (i) treated patient information, (ii) efficacy at 6 months and (iii) efficacy at 12 months
** Continuous efficacy evaluation necessary through age based motor function evaluation tools (e.g., CHOP-INTEND)

As of June 2023, KYMRIAH and ZOLGENSMA are reimbursed at 85% and 77%, respectively, of the average price of the A8 countries (UK, US, Italy, France, Germany, Swiss, Japan and Canada) referenced by the Korean government[2]. ZOLGENSMA's prior approval rate since its listing is at 80%[3].

CONCLUSIONS

With the continuous launch of high priced drugs, the Korean government has announced high priced drug P&R policies aimed at increasing health insurance efficiency and patient access. Continued assessment on whether the government can indeed achieve these two policy objectives by strengthening post-listing management (rather than delayed listing) is necessary.

References

1. [MOHW website] https://www.korea.kr/news/pressReleaseView.do?newsId=156517438
2. Refer to the A8 country list prices according to Korean P&R regulations: (Japan's Hokenyaku Jiten (Yakugyo Kenkyukai), France's Vidal, Germany's Rote Liste, Italy's L'Informatore Farmaceutico, Switzerland's Arzneimittel Kompendium, UK's MIMS, and the USA's Red book and Canada's Ontario)
3. [HIRA website] https://biz.hira.or.kr/index.do?sso=ok