

South Korea

Recent and planned developments in pharmaceutical policies 2018

Special topic: national incentives and derogatory procedures for orphan medicines

CHANGES IN PRICING

No changes in pricing

CHANGES IN REIMBURSEMENT

- **Benefit coverage range expansion of anticancer drug**
 - bevacizumab(AVASTIN®)'s coverage range was expanded to second treatment of Ovarian Cancer(2018.5.1.)
 - blinatumomab(BLINCYTO®)'s coverage range was expanded to acute lymphoblastic leukemia(2018.7.1.)
 - ceritinib(ZYKADIA®)'s coverage range was expanded to first treatment of non-small cell lung cancer(2018.11.1.)

OTHERS CHANGES

- Change of Anticancer therapy beyond permission range(initiated in July, 2018)
 - To use of off-label anticancer drugs need pre-approval of Cancer Deliberation Committee, because of some concerns about efficacy and toxicity.
 - Post-approval system is introduced for end stage cancer patients in need of fast treatment.
 - Expand from hospital established Multidisciplinary committee to hospital using Common Use Multidisciplinary Committee or linked provider's Multidisciplinary Committee.
 - Change from approval to notification for pre-admission therapy.

SPECIAL TOPIC: National Incentives and Derogatory Procedures for Orphan Medicines

- Incentives have been set in the *RARE DISEASE MANAGEMENT ACT* and the Minister of Health and Welfare shall formulate a comprehensive rare disease management plan every five years.
- **List** : According to the *Rare Disease Management Act*, the Ministry of Health and Welfare(MoHW) has designated a list of 927 rare diseases on September 2018, a disease that affects fewer than 20,000 people, or whose number of carriers is unknown because diagnosis of the disease is difficult. The Ministry of Food and Drug Safety(MFDS) designates an orphan drug in accordance with the regulations on the designation of orphan drugs.
- **Research and development** : The rare disease support center established by the Minister of Health and Welfare perform inspection of and research on the occurrence, prevention, treatment, etc. of rare diseases, and support therefor
- **Availability** : Korea Orphan and Essential Drug Center supply the orphan drugs hard to be supplied.
- **Listing and Pricing** :
 - 69 drugs for rare disease were applied and 56 were listed from 2014 to July 2018.(81%),
* anticancer(72%), non rare disease & non anticancer(83%)
 - Drugs for rare diseases and those that meet the condition of clinical need, difficulty of producing evidence, listed in foreign country, can receive assessment without economic evaluation results.
 - Drugs for rare diseases, which do not have alternative drug and are used for life threatening condition, have flexible ICER. And they can contract to Risk Sharing Agreement(RSA).
- **Co-payment** : Since July 2009, the government has provided the rare incurable patients with financial support by reducing the medical expenses by means of the national health insurance. The statutory co-insurance rate of the national health insurance is 10 percent for the registered rare incurable patients. Separately, low-income patients are provided with the subsidy program.
- **Assessment of orphans** : Drugs for rare diseases are evaluated by the committee within 100 days of receiving the application. Usually it's 120 days.