ISSN:1738-6764, eISSN:2093-7504

A Matter-of-fact Way to Health Insurance Coverage for New Health Technologies

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https://doi.org/10.5392/IJoC.2024.20.2.033

Manuscript Received 5 March 2024; Received 20 June 2024; Accepted 25 June 2024

Abstract: *New health technologies are as the state-of-the-art in the modern medicine and health care that can be applied to various systemic diseases. Regardless of its importance, in many cases the patients are not being able to benefit from new health technologies for their systemic diseases. Hence, they are not covered under health insurance generally, and even covered, it is common that long time is taken to be covered. This study looks at different perspective to the number of previous studies on regenerative medicine as an exemplary case and health insurance coverage, which focused on the clinical results that was beneficial to the patients, researchers and society. In this study, the insured benefits and various non-insured benefits under the health insurance system were examined. Even some regenerative medical services are recognized as safety and efficacy to some degree, the problem of being treated as non-insured medical services due to the new health care technology as itself was discussed through the concept of shadow price. In addition, the study discussed that regenerative medicine proven effectiveness for disease treatments should be included in the insurance benefits, in principle. For this, Japanese cases were referred. The case of Japan may not be fully applicable to all other countries or some specific countries. However, it may be a reference for countries with low protection even though taking public medical insurance systems.*

Keywords: New health technology; Health insurance coverage; Regenerative medicine; Shadow price

1. Introduction

The regenerative medicine can be used as treatment option to save patient' life from the systemic disease. The medicine is state-of-the-art in the modern medicine that can be applied to various systemic diseases. However, regardless of its importance, the patients are not being able to benefit from the regenerative medicine for their systemic diseases. Because, its clinical studies are currently in progress and its effectiveness or the harm and its safety is not yet proved, hence, the regenerative medicine is not covered under health insurance.

This study looks at different perspective to the number of previous studies on regenerative medicine and health insurance coverage, which focused on the clinical results that was beneficial to the patients, researchers and society.

2. Materials and Methods: Health insurance coverage

Generally, medical expenses are comprised of benefit covered by the health insurance and non-claimable part where patient is responsible for. Mostly, those of health care technologies or medical practices are accepted based on its effectiveness, safety, and economic efficiency, especially for the ones that are eligible to be covered by the health insurance [1]. Economic efficiency simply means, the services are acceptable within the scope of health insurance finance, which is not expensive or has no effects on other services to be covered by health insurance. Also, to be covered by the health insurance, it should be assumed that the services are relatively cost-effective than the alternatives in those cases of the equal severity for the same disease.

However, rather than categorizing the health care expenditure by a simple dichotomous of the health insurance coverage and the non-coverage. Various forms of classifications are available globally. The most common ones are conditional coverage and selective coverage [2, 3]. In the cases of that services are not suitable

for one or more for the criteria of effectiveness and safety, or economic efficiency, services are categorized as conditional coverage or selective coverage even though the criteria or classifications are completely different among countries. To be considered to fall into the category of conditional coverage or selective coverage, it's not just consider the cases mentioned above, but also timeless or equity also takes into the consideration.

Basically, public health insurance in the US, such as Medicaid, is for people in need of financial support, that is, low-income people [4]. However, people who need medical assistance but are not eligible for public medical aids may also be eligible for public medical assistance. This is also the same under the public health insurance system, which is a conditional coverage [5].

Whether or not the patient has the ability to pay for medical care, whether or not he or she is insured, and whether or not the medical service he or she wants to use is covered by the insurance benefit, if the necessary medical care is sufficiently provided, this would be ideal for the patient [6]. However, in many cases, the medical service that the patient wishes to use is not included in the insurance benefit, so that the patient cannot use the medical service for financial reasons. In this case, the healthcare provider may require the insurer to provide the service as an insurance benefit. Then, in consideration of the medical needs and insurance financial burden, the service can be included as a general service of the insurance benefit, which can be called selective coverage [1], [7].

Generally, services that are covered by conditional coverage or selective coverage are recognized as new health care technologies. A new health care technology is the technology that is emerging in its development and use, and it can have a great influence on the treatment of patients [8]. A "new" health care technology is a term contrasted with existing health care technology, but in order to evaluate new health care technology, it has to be compared with existing health care technology, so that it is generally referred to as just "health care technology".

In many cases, despite of its accreditation on effectiveness and safety, health care technologies have an insufficient clinical evidence from the clinical reviews or showed unrespectable criteria. Most of the regenerative medicines are the examples.

Though it is associated with patient' medical treatment for this, and an expense can be caused, cost sharing is required between patients and researchers. That is because new health care technology such as regenerative medicine is often not included in the insurance, but it contributes not only to the patient's therapeutic purpose, but also to the researcher's research. To lessen the burden of cost on both sides, health insurance coverage is necessary.

Market prices formed in perfect markets, represent true social values. However, in the case of new health care technologies including regenerative medicine, that is public services, because healthcare providers do not adequately supply services and patients do not consume as much as they want, it cannot do. The price that the market does not reflect a true social value is the shadow price. In other words, when loss of benefits occurs because of no insurance coverage for regenerative medicine, the loss is called "shadow price" in economics [9]. In health care, this concept can be derived.

In Figure 1, the supply and demand curves in the complete market are balanced at the point A. The price at this point is "Price with insurance" and the demand is "Quantity with insurance." However, at the point B made by the supply and demand under no insurance coverage for regenerative medicine, the price is "Shadow price" and the demand is "Quantity without insurance." That is, when regenerative medicine is not included in insurance, there is a social cost in which the price is higher than the normal social value but the demand amount is smaller. This shows that regenerative medicine should be covered by insurance.

3. Results

3.1 Regenerative medicine health insurance coverage

The regenerative medicine is currently the translational research that is finally designed to be a pragmatic clinical research, and it may be said that this is a convergence study for the public benefit. The study of the public benefit needs a support, to develop in a practical use in clinical study. In other words, it should be utilized practically in the clinical fields and produce much advantage socially. To do so, studies that is related to regenerative medicine should not only be just a "study" but also "treatment" for patients by the inclusion of insurance.

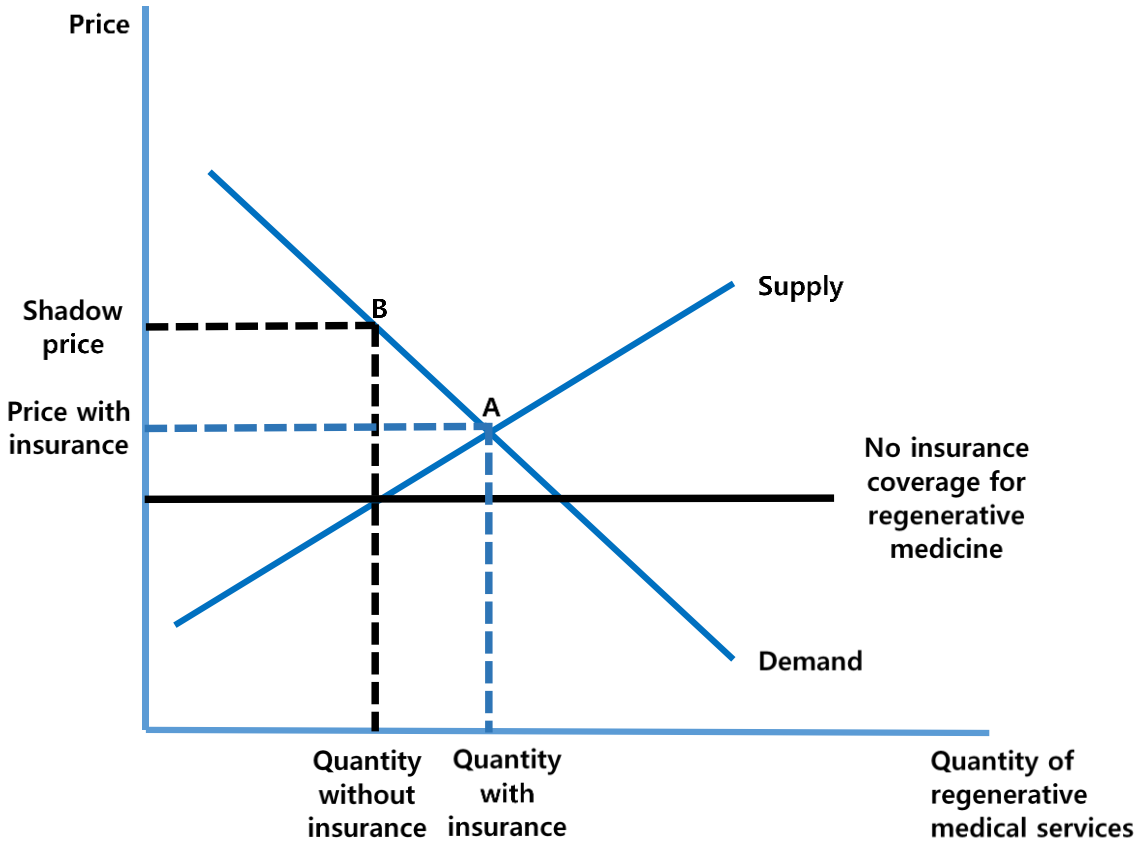

Figure 1. Social costs by no health insurance coverage for regenerative medicine

The number of studies for curative effect and improvement for rare intractable disease patients are conducted around the world [10]. However, it seems to be difficult to overcome some diseases. It is expected that regenerative medicine to be able to raise the possibility of full recovery for these patients at present [11]. The reason is that, a result of clinical trials using regenerative medicine have been appeared to show the possibility of complete recovery from the illness, as well as improving quality of life and not only prolonging life years.

The reason appears successively with results of clinical trials showing possibility of the complete recovery from the treatment for a disease using regenerative medicine, and as a result, this enables to improve beyond the life extension and raw quality improvement. The benefits from regenerative medicine are beneficial for patients mitigating burden of medical expenditure and for the society. Obviously, health insurance coverage for the study and treatment by regenerative medicine must be premised to make it possible.

Under the consideration of certain criteria of effectiveness and safety of regenerative medicine, use of uninsured services together with insured ones is acceptable by the advanced medical service system. This institutional framework of timely approval can make people receive proper services paying an acceptable level of payments.

3.2 An exemplary case: Japan

In Japan, mixed private and insurance payments are not allowed for medical services [12]. So that, in case of using uncovered medical services by health insurance, the insured should pay for nay even medical services covered by medical insurance, though some highly advanced medical services are exceptionally allowed for mixed payments. In 2000s, as requirements for promoting economic vitalization and widening patients' choices of medical services increased, exceptional approval for mixed payments was expanded [13].

Within the Japanese health insurance system, advanced medical services those are allowed to use in combination with insured and uninsured medical services are categorized by Advanced medical services A and B. The Advanced medical services A should not be involved to use any drug or medical equipment not being approved for outer range of approved application. This technology involves the use of extracorporeal diagnostic

agents, but the influence on human bodies by the relevant agents is insignificant. The Advanced medical services B can be involved to use drug or medical equipment not being approved for outside of approved application. This technology requires attentive evaluation for use on the basis of safety, effectiveness and any relevant side effects unexpected when implementing. Regenerative medicine comes under this technology.

As other insurance benefits, regenerative medical services within insurance coverage, medical expenses consist of insurer's burden and patient's out-of-pocket payment. However, even in this case, mixed treatments with covered and non-covered services are prohibited. In principle, regenerative medical services that are not covered by insurance benefits cannot be used in combination with covered and non-covered services. If used, the patient is responsible for all medical costs, not just for regenerative medical services, but also originally for insurer's burden. There is no difference between the Advanced medical services A and the Advanced medical services B. As of May 2017, the number of regenerative medicine under clinical studies is 66, out of 676 Advanced medical services B items.

The regenerative medicine is divided into three types up to safety. Type 1 is the technologies with the high risk having not been carried out by a person, e.g., embryonic stem cells or iPS cells. Type 2 involves technologies currently being used with a medium level of risk, such as somatic stem cells. Type 3 is the manufactured materials from stem cells with low risk, for example, processed somatic cells. There is no difference in the use of Type 1, Type 2 and Type 3, but the procedure for obtaining permission is different. Type 1 has a complicated screening process and Type 3 is relatively easy.

4. Discussion and Conclusions

In this study, the insured benefits and various non-insured benefits under the health insurance system were examined. Even some regenerative medical services are recognized as safety and efficacy to some degree, the problem of being treated as non-insured medical services due to the new health care technology as itself was discussed through the concept of shadow price.

In addition, the study discussed that regenerative medicine proven effectiveness of disease treatments should be included in the insurance benefits, in principle. For this, Japanese cases were referred. The case of Japan may not be fully applicable to all other countries or some specific countries. However, it may be a reference for countries with low protection even though taking public medical insurance systems.

As there is evidence that expanding health insurance coverage can prolong lives, escalating health insurance reimbursement including new medical technologies is important [14, 15]. However, the reality is that there are various limitations to expanding health insurance benefits. Therefore, the key is how to resolve the trade-off between salary expansion and budget constraints [16]. These are not the matters of responsibility or agreement between individual patients or medical staff or medical institutions, but those for which the state or society is responsible [17].

Acknowledgment: This study was supported by Hyupsung University (Research Fund 2023-0041)

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