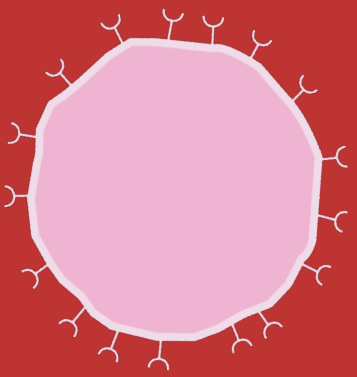
Health system readiness for radioligand therapy in the ROK

SITUATION ANALYSIS REPORT

August 2023

This report was developed by GR Korea in collaboration with a ROK Expert Advisory Group. It details findings from the ROK application of the Radioligand Therapy Readiness Assessment Framework, an international tool developed by The Health Policy Partnership. The group has had full editorial control over all national-level outputs. The project is supported through an unrestricted grant from Advanced Accelerator Applications, a Novartis Company.

GR Korea



ABOUT THE RADIOLIGAND THERAPY READINESS ASSESSMENT PROJECT

This report was developed by GR Korea in collaboration with a ROK Expert Advisory Group. It is part of a broader piece of work aiming to define what is needed to establish system-level readiness for radioligand therapy in the ROK. It is supported by other documents, including a policy action blueprint on health system readiness for radioligand therapy in the ROK and an associated national framework, which was adapted from the Radioligand Therapy Readiness Assessment Framework, developed by The Health Policy Partnership. For more information about health system readiness for radioligand therapy, and The Radioligand Therapy Readiness Assessment Framework, please visit **www.radioligandtherapy.com**

ACKNOWLEDGEMENTS

With many thanks to our ROK Expert Advisory Group members:

- **Dr. Kang Keon-wook**, Professor of Nuclear Medicine, Seoul National University Hospital and President of the Korean Society of Nuclear Medicine
- **Dr. Yoo Chang-hoon**, Professor of Medical Oncology, Seoul Asan Medical Center
- **Lee Ug**, Senior Consultant of Healthcare Practice Group, Lee & Ko
- **Dr. Chung Weon-kuu**, Professor of Radiation Oncology, Kyung Hee University Hospital at Gangdong and CEO of RADICURE
- **Choi Young-eun**, Director of Supply Management Division, Korea Orphan & Essential Drug Center
- **Dr. Hyun Seung-hyup**, Professor of Nuclear Medicine, Samsung Medical Center
- **Hwang Won-jae,** President of the Korean Association of Neuroendocrine Tumor

ABOUT GR KOREA

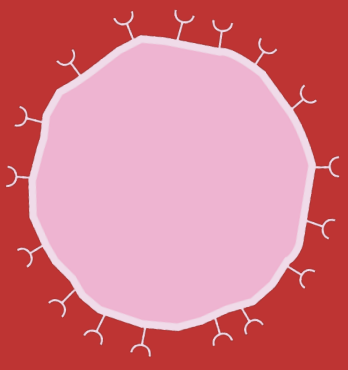
GR Korea provides a full range of government relations and public affairs services, combining deep understanding of Korean government decision-making with business sense and dedication to the clients' public affairs goals. GR Korea is a proud part of The GR Company, the largest dedicated government relations and public affairs consultancy in Korea and Japan, with offices in Seoul, Tokyo, Osaka, Washington D.C. and London.

ABOUT THE HEALTH POLICY PARTNERSHIP

The Health Policy Partnership (HPP) is an independent research organisation, working with partners across the health spectrum to drive the policy and system changes that will improve people's health.

PLEASE CITE AS: GR Korea. 2023. *Health system readiness for radioligand therapy in the ROK: situation analysis report.* Seoul: GR Korea.

Contents



Foreword

Radioligand therapy is a highly precise targeted therapeutic approach to cancer treatment which has recently caught the attention of the medical society as the next-generation anti-cancer treatment to treat refractory cancer. In particular, radioligand therapy has shown remarkable effectiveness in increasing odds of survival and improving quality of life of patients with neuroendocrine tumors (NETs). It is also being researched as a new treatment option for some patients with malignant lymphoma and prostate cancer, and the results are expected in the near future.

In the Republic of Korea (ROK), radioligand therapy was introduced starting from the introduction of radioimmunotherapy drug for non-Hodgkin's lymphoma in 2002, to more recently the radionuclide therapy drug for NETs in 2020. With the latest innovative medical technologies, radioligand therapy is expected to continue developing rapidly, and naturally the demand for radioligand therapy is likely to increase exponentially in the future.

However, to increase accessibility to new treatments such as radioligand therapy, and to achieve the ultimate outcome of higher cancer survival rates, policy considerations and integration of emerging treatments like radioligand therapy into the existing healthcare system are necessary.

In the absence of these, inadequate policy framework, lack of medical infrastructures and services, and limitations in health insurance reimbursements persist as practical barriers to radioligand therapy treatment access. This is exemplified by the fact that radioimmunotherapy was introduced in the ROK more than 20 years ago, and that many cancer patients are still unable to locally access this high-quality, innovative cancer treatment.

Therefore, the first step is to provide a systematic and multifaceted analysis of the current policy framework, regulations, national health insurance coverage, demand, and practices to identify areas in need of improvement. Then, it is important to make and implement policies based on a comprehensive policy blueprint derived from research.

This report aims to provide a comprehensive assessment of radioligand therapy in the ROK and provide insight into the current gaps in the country's healthcare systems as relates to radioligand therapy. Based on these findings, this report will identify areas in need of policy discussions. Finally, the aim is to increase patients' access to radioligand therapy treatments, and to increase stakeholders' awareness and understanding of these treatments, so that policies governing such innovative treatments can be implemented for more indications in the future.

A multidisciplinary group of advisors from ROK academia, policy, and the medical profession was convened for the purposes of, and participated in, the preparation of this report. Through a series of in-depth, multidisciplinary discussions, the group of advisors provided an informed, detailed picture of the local radioligand therapy status quo. The purpose was to incorporate inputs from a wide range of radioligand therapy experts, including nuclear medicine physicians, healthcare professionals, pharmacists, legal advisors, and patient organization representatives.

Lastly, we would like to thank and remember the late Mr. Hwang Won-jae, President of Korean Association of Neuroendocrine Tumor (KANT) and a member of the ROK advisory group, who generously shared his experience and challenges of radioligand therapy as a patient. It is our hope that this report helps prompt health policy discussions and facilitate planning for radioligand therapy, contributing to wider health system readiness.

Kang Keon-wook,
Seoul National University Hospital

Yoo Chang-hoon,
Seoul Asan Medical Center

Lee Ug,
Lee & Ko

Chung Weon-kuu,
Kyung Hee University Hospital at Gangdong

Choi Young-eun,
Korea Orphan & Essential Drug Center

Hyun Seung-hyup,
Samsung Medical Center

Executive Summary

Radioligand therapy is a highly targeted cancer treatment that aims to cause DNA damage to target cancer cells to suppress tumor growth and replication. The treatment administers a drug that links ligands (a substance that specifically binds to protein molecules) designed to target cancer cells with a particular surface molecule, and that contains a radioisotope (RI) to kill cancer cells via nuclear radiation.[1,2]

Radioligand therapy can deliver the given radioisotope to selectively neutralize target cancer cells with radiation, while minimizing damage to surrounding healthy cells. This makes the treatment distinct from existing biological and chemical agents used to treat cancer[1,11,12] and has been shown to increase survival and improve health-related quality of life for certain types of NET patients, as well as the patients of lymphoma and prostate cancer. [3-10]

In the ROK, radioligand therapy is currently approved for use as a treatment for some NETs and non-Hodgkin's lymphoma[13,14] and has since been prescribed with limited reimbursement for other cancers by the Ministry of Food and Drug Safety (MFDS).[15] Contrary to this restrictive regulatory status, research is actively underway in the medical field to expand treatable indications. Hence, the treatment is expected to be applied to a wider range of cancer patients in the future.[16]

For radioligand therapy to expand in the ROK, however, changes in the domestic healthcare system are necessary. In other words, radioligand therapy-related infrastructure needs to be properly integrated into all parts of the existing healthcare system. Planning for the expansion first requires a prospective plan established through multidisciplinary and multi-sectoral evaluation. Throughout this process, stakeholders must actively work together, and above all, government-level efforts must ensure that the most effective emerging treatments are made available to all those who could benefit from it.

THE ROK WILL NEED TO COMMIT TO:

- **Raising awareness on radioligand therapy** among patients, medical professionals, and policy decision-makers
- **Encouraging joint-ministerial cooperation & governance** to provide a national policy that includes radioligand therapy
- **Securing Korean-context clinical data** to initiate the development of national clinical guideline including radioligand therapy
- **Constant supporting for radioisotope-related infrastructure and licensing issues** for domestic expansion of the use of radioligand therapy
- **Introducing the new product approval process** that reflects the characteristics of radiopharmaceuticals
- **Expanding the financial support for patients and medical professionals** by increasing reimbursement and fee for service

Introduction

What is radioligand therapy?

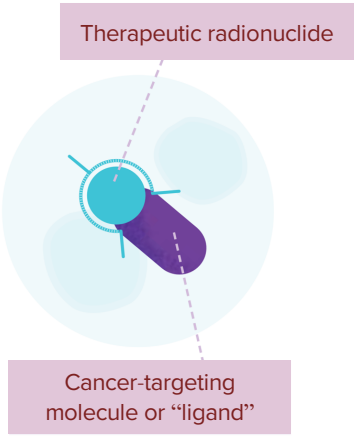


FIGURE 1. Radioligand

Radioligand therapy is a highly targeted cancer therapy. A radioligand is made of two parts: a ligand, which binds to cancer cells that present a particular surface receptor, and a radionuclide, which neutralizes the cancer cell via radiation (Figure 1)[1,2]. When a ligand that recognizes a specific protein presented in cancer travels through the bloodstream and binds to cancer cells, it then emits radiation to kill them. In contrast to existing cancer treatments that damage not only cancer cells but also healthy non-cancer cells, radioligand therapy can treat cancer with minimal damage to healthy cells.[1,11,12] In addition, since the treatment is not limited to a specific organ or form of cancer, it can be applied whenever a cancer-detecting ligand is developed. Thus, it has recently attracted attention as a technology that can be widely applied to more and more cancer indications in the future.

Diagnosis is more common than treatment in the ROK when it comes to radiopharmaceuticals. Hundreds of thousands of nuclear medical imaging procedures are conducted every year in the ROK.[17] As of 2020, 186 Positron Emission Tomography (PET) devices are in operation in the ROK, which is about 3.6 PET scanners per 1 million people, well above the OCED average (2.4 PET scanners).[18] On the other hand, radioiodine was introduced in the ROK in the 1960s to treat benign thyroid diseases, but only 8.2% of the target patients were prescribed,[19] and radioimmunotherapy prescriptions for lymphoma introduced has remained significantly lower than in other developed countries in the two decades since it was introduced.[19-21]

> **The report will use the term radioligand therapy**, but the same terms describing the therapy include radiation missile therapy, radionuclide therapy, molecular imaging precision therapy, peptide receptor radionuclide therapy (PRRT), systemic radiation therapy, targeted radioisotope therapy, and targeted radiation therapy. If the ligand used is an antibody, the treatment is also called radioimmunotherapy.

However, in recent years, new drugs using radioligand therapy have achieved remarkable results, attracting a lot of attention. As radioligand therapy applications for NETs have proven highly effective – on average extending the entire survival period by about 18 months[3] - demand for the treatment is increasing in the ROK. Also, radioligand therapy approval for prostate cancer, which is currently under review and will likely be available in the nearest future,[22] would increase the number of patients that are eligible for the therapy. As the treatment is considered a new paradigm in cancer treatment, the ROK government and private sector are both increasingly active in developing therapeutic drugs using radioisotopes.[16 23 24]

The use of radioligand therapy

In the ROK, radioligand therapy is currently approved by the MFDS for non-Hodgkin's lymphoma and gastro-entero-pancreatic neuroendocrine tumor (GEP-NET) indications.[13 14] However, the only indication that is reimbursed by the Health Insurance Review and Assessment Service (HIRA) is GEP-NET.[15] Radioligand therapy for non-Hodgkin's lymphoma has been considered multiple times for nationalized reimbursement but failed to pass review due to low cost-effectiveness. In addition, radioligand therapy use for lymphoma is less common since effective alternative drugs are widely prescribed such cases.[20 25]

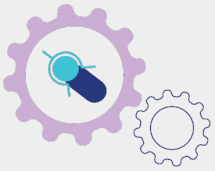
Radioligand therapy is expected to be applied to the treatment of prostate cancer soon, and it is expected to be available for more patients in the future. In June 2023, MFDS designated a radioligand therapy for metastatic castration-resistant prostate cancer (mCRPC) as a drug subject to Global Innovative product on Fast Track (GIFT).[22] This will shorten the product approval period by up to 75%, so it is expected to be introduced in the ROK faster than general drugs.[26] Prostate cancer is one of the six major cancer diseases in the ROK, accounting for 6.8% of all cancer cases, and the prevalence is 234.5 per 100,000 patients. As there are on average 16,000 new patients every year,[28] the expansion of the treatment with prostate cancer as indication will affect more patients in the ROK.

Preparing for the future

Radioligand therapy is expected to continue to expand in the future. Currently, many studies are being conducted in the ROK and abroad to expand indications treatable with radioligand therapy or for early treatment.[29-36] In general when the U.S. or Europe expands product approval or indication of any treatment, the ROK tends to do the same.[36] This makes it likely for example that radioligand therapy for mCRPC, metastatic breast cancer, and central nervous system metastatic cancer (neuroblastoma, etc.) which are currently undergoing clinical testing in the U.S, are likely to be introduced in the ROK in the future. In addition to the ongoing research cases, as described above, radioligand therapy is a technology that can be applied to various cancers[22] and has many advantages in terms of patient health.

However, in order for radioligand therapy to reach ROK patients at scale in the future, ensuring system readiness for the introduction of radioligand therapy is needed. Readiness for radioligand therapy means that the necessary personnel, policies, processes, infrastructure, and resources are in place to facilitate its prompt adoption into clinical practice. In addition, these factors must have sufficient flexibility to ensure that the approach can be integrated in the most effective way in an ever-evolving context. To achieve readiness for radioligand therapy in the ROK, the Radioligand therapy Readiness Assessment Framework was used an approach template for systematic analysis (Box 1). It is built around five domains: governance, regulation, and reimbursement, identified need, service provision, and health information. Based on this framework, the ROK expert advisory group reached consensus on a total of six policies necessary to ensure country-level radioligand therapy readiness.

BOX 1.



What do we mean by integration and readiness for radioligand therapy?

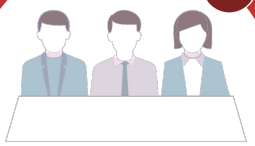
Integration is the adoption and assimilation of radioligand therapy into every aspect of a health system (i.e., governance, regulation, reimbursement, funding, and service delivery frameworks) in order to ensure its availability to all people who may benefit from it.

Readiness is the ability of the health system to rapidly and sustainably adapt policies, processes, and infrastructure to support integration of a new radioligand therapy.

Integration and readiness for radioligand therapy: strategic challenges

1

Awareness

2

Cooperation and governance

3

Clinical guideline and data

4

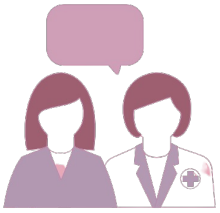
Infrastructure and licensing

5

Product approval process

6

Financial support



Awareness

There is mixed awareness of radioligand therapy among people who might most benefit from it. There are many terms for radioligand therapy, including radio missile therapy, radionuclide therapy, molecular imaging precision therapy, and peptide-receptor radionuclide therapy (PRRT). Clinical indications that are treatable by radioligand therapy in the ROK currently are limited to non-Hodgkin's lymphoma and adult GEP-NET. First, radioimmunotherapy for non-Hodgkin's lymphoma was introduced in the ROK in 2005 following U.S. FDA approval in 2002,[13] but it was not widely recognized as a necessary drug for treatment since it did not prove cost-effective compared to alternative drugs, and was never registered for reimbursement under the ROK's nationalized healthcare scheme.[20 25]

In addition, due to the widespread prescription of alternative drugs in the ROK, and the fact that there are still few hospitals equipped with preparation and delivery mechanisms for radioimmunotherapy, lymphoma patients are less aware of the fact that radioligand therapy is possible.[37 38] On the other hand, patients with NETs argued for the need to introduce radioligand therapy even before its introduction in the ROK [39-43] up until it was approved in 2020 (and eventually approved for insurance benefits relatively quickly in 2022).[14 15] Thus, patient awareness of radioligand therapy is relatively high.

For example, the Korean Association of Neuroendocrine Tumor (KANT) which consists of about 2,500 people, is active in raising awareness of the treatment by exchanging various information on individual progress of radioligand therapy treatment cycles and latest clinical research papers on clinical indications. In addition, the association provides regular education for patients and guardians on its own, and actively meets with stakeholders.[44] In the case of prostate cancer, which is another indication where radioligand therapy is known to be effective, treatment awareness is relatively low since radioligand therapy currently not approved in the ROK for prostate cancer treatment and – most significantly - patient advocacy is nearly absent.[22 26]

"Even for common cancers with high incidence rate, such as prostate cancer, the frequent leadership absence of patient associations due to their physical limitations hampers patient-led awareness raising activities for the expansion of radioligand therapy."

Dr. Kang Keon-wook
Seoul National University Hospital

Medical professional's perceptions of radioligand therapy also varies greatly. NETs are known to be a cancer with a higher incidence than colon cancer in western countries but are still relatively rare in East Asia, making them underdiagnosed. In the past, NETs were often misdiagnosed as different cancers depending on the disease-producing organs, and physicians at primary and secondary hospitals as well as the general public are still mostly unaware of the different types and risk factors related to NETs.[45]

"In smaller regional hospitals where the treatment does not take place due to the lack of infrastructure, even nuclear medicine physicians remain largely unaware of the existence of radioligand therapy. "

Hwang Won-jae
Korean Association of Neuroendocrine Tumor

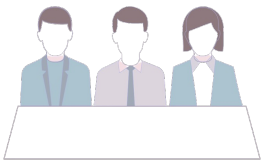
In fact, physicians are exposed to radioligand therapy for only 3-4 hours during the entire four-year curriculum in medical school,[46] and because it is a new technology that has only been introduced in the ROK for 3-4 years with rare cancers as indication, understanding of this treatment is very low among other clinical staff not specialized in nuclear medicine. To improve this, the Korean Society of Medical Oncology (KSMO) and the Korean Society of Nuclear Medicine (KSNM) are actively informing more physicians of the effectiveness and safety of radioligand therapy for treatment of NETs.[47-49]

"Because physicians at primary care facilities have little knowledge on this new targeted therapy, some patients who would have been benefited are not introduced to radioligand therapy and missed to be referred."

Dr. Chung Weon-Kuu
Kyung Hee University Hospital at Gangdong

The low understanding and awareness of radioligand therapy among government stakeholders is also an obstacle to the spread of the treatment.[45] Government agencies that have a major influence on the domestic medical field are mainly MFDS, HIRA, which evaluates the appropriateness of drugs in health insurance, the National Health Insurance Service (NHIS), which conducts negotiations with pharmaceutical companies over drug prices, and Division of Pharmaceutical Benefits under the Ministry of Health and Welfare (MOHW), which presents policies across all of these institutions.

In addition, decision-makers who have direct influence on policymaking and revision of laws, such as lawmakers belonging to the National Assembly's Health and Welfare Committee also have a great influence in revising related laws and easing regulations. However, none of these domestic policymakers fully understand – much less support – radioligand therapy as an effective cancer treatment. Ones that have experience practicing product approval and reimbursement for the treatment are aware of what it is, but it is usually only recognized as a type of chemotherapy, and there is no consensus on establishing and promoting policies for the treatment.[50]



Cooperation and governance

Regulations related to radioligand therapy do not reflect the reality of patients in need of benefits, and therefore need major changes. Yet, there is a lack of momentum to move government stakeholders in this direction. In the case of radioligand therapy currently available in the ROK, the target, frequency, and timing of dosage covered by national health insurance are limited, which makes it difficult to administer the full treatment cycle to patients on a tailored basis.[51] [52] The first step toward addressing this issue is to draw attention from government stakeholders via mobilizing patient advocacy groups and leveraging consensus from relevant academic societies.

However, NETs have domestic prevalence rate of less than 1.5 per 100,000 people[53] and an incidence rate of only 2,500 per year.[45] Therefore, not only is the size of the NET patient association itself small, but patients in the process of actually fighting the disease inevitably have significant limitations on their physical activity level, resulting in lack of capacity to lead active external cooperation activities.[54] In addition, in the case of nuclear medicine, the department responsible for administering radioligand therapy treatments, according to National Health Insurance Statistics in 2022, there are only 257 nuclear medicine physicians in the ROK.[55] Recording the lowest application rate of 13.8% in the 2023 1st semester resident physicians' recruitment, for example, they are one of the smallest groups of medical experts, and therefore even at the level of medical providers, are not of practically sufficient size and capacity to meaningfully and effectively engage government stakeholders.[56]

"Government stakeholders like MOHW, HIRA, and NHIS only perceive radioligand therapy as one of many cancer treatments, with no specific significance necessitating action or expand its use in the country."

Lee Ug
Lee & Ko

Therefore, in order to bring about policy changes, civil society stakeholders such as KANT and the KSNM should first raise awareness of radioligand therapy through communications with larger more generalized patient groups, and then communicate with stakeholders via leverageable consensus. For example, at the academic level, the KSMO and the KSNM are already contributing to policy changes by submitting opinions to the HIRA.[57] [58] In addition to NET indications, radioligand therapy is expected to expand to prostate cancer soon,[21] [25] so the Prostate Cancer Patient Association (PSA Korea), Seoul National University Hospital's nuclear medicine department, and KSNM are jointly working together to preemptively raise awareness of radioligand therapy.[59] These sorts of cross-sector stakeholder activities will be necessary to create momentum toward policy change.

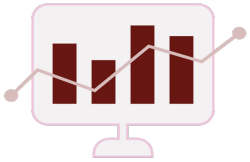
Radioligand therapy is currently defined under the regulatory scope of radioisotope policy, not within the cancer management policy. This creates redundancies where radioligand therapy cannot be dealt within the context of disease-specific policies. The ROK's current national-level cancer policy framework is the 4th National Cancer Control Plan (2021-2025), and the plan is amended every five years.[60] The policy does include indications that are treatable by radioligand therapy but does not recommend radioligand therapy as a priority treatment method.

Policies related to radioligand therapy are classified as radiation technology and fall under the scope of the "The 3rd Radiation and Radioisotope Use Promotion Plan (2022-2026)," and overseen by the Ministry of Science and ICT (MSIT).[61] The ministry's policy on radiopharmaceuticals research focuses on fostering new technologies from an industrial point of view rather than treating patients, so the latter angle is largely underplayed and/or omitted.[59] [62] In other words, under the current framework of domestic policies where radiation therapy is managed by MSIT (instead of MOHW) due to its technical aspects, radioligand therapy is often not included even if a disease-specific policy is released by agencies like MOHW.

"In the ROK, MOHW is leading disease-specific policies, while MSIT supports the research for nuclear medicine and radiation oncology as a part of radiation policies. This creates policy silos for radioligand therapy, and there is no cross-ministry communications for radioligand therapy."

Dr. Kang Keon-wook
Seoul National University Hospital

This is also a testament to the fact that new medical technologies are emerging one after another with the development of science and technology, but at the current level, disease-specific policies are not keeping up with this pace; so-called regulatory lag.[63] Therefore, for these new technologies to be quickly applied to the medical field, cross-agency communication and collaboration are needed - and specifically to expand radioligand therapy, inclusive policies, plans, related R&D, and practical budget support from MOHW and MSIT will be needed.



Clinical guidelines and data

Currently, there are no clinical guidelines for NETs and lymphoma for radioligand therapy in the ROK. Here, clinical guidelines refer to statements systematically developed to help doctors and patients make treatment-related decisions in specific scenarios.[64] Usually, domestic cancer-related clinical guidelines are developed or reviewed under the leadership of the National Cancer Center (NCC) or the Korean Academy of Medical Sciences (KAMS), and in consultation with multidisciplinary societies related to specific indications who participate in drafting guidelines.[65] [66]

Clinical guidelines for NETs have not yet been developed to reflect the current situation in the ROK, and **thus in practice the US National Comprehensive Cancer Network (NCCN) and European Society for Medical Oncology (ESMO) guidelines are frequently referenced when conducting radioligand therapy for NETs in Korea.**

Since there is no significant difference in treatment results whichever of these two regional frameworks is applied, radioligand therapy is recommended based on the two guidelines in consideration of the standard practice treatment environment, reimbursement standards, and patient awareness. The most similar type of reference document to the current treatment guidelines for NETs is a white paper written by members of the KSMO to explain the classification of NETs in the ROK and the application of radioligand therapy in the ROK.[70] However, the paper is not recognized as an official clinical guideline approved by the Korean Academy of Medical Sciences. As prostate cancer is relatively common - ranked sixth with 6.8% of all cancer cases in the ROK as of 2020 - there are officially recognized clinical guidelines through the Korean Academy of Medical Sciences' evaluation,[71] [72] whereas radioligand therapy is not yet allowed as a prostate cancer treatment and hence is not recommended under the clinical guidelines.

The domestic medical community is not actively involved in the development and utilization of clinical guidelines which play an important role in standardized treatment and evidence-oriented medicine.[73] The biggest reason for this is the difficulty of securing data reflecting the local contexts and environment. In order to develop clinical guidelines suitable for the ROK context, it is essential to first identify epidemiological characteristics and review the effectiveness of treatment methods within the domestic healthcare environment. However, it is noteworthy that with rare diseases such as NETs, it is difficult to conduct clinical research in the ROK,[74] and even with more common forms of cancer such as prostate cancer, there is little causal data to draw from, making it difficult to draft appropriate clinical guidelines.[72]

"Since there is no NET-specific academic society in the ROK, the challenge even begins with the question – 'who is going to - or has to - lead such a time-consuming process of clinical guideline development?' It usually needs approximately 100 physicians with a 3-year time period."

Dr. Yoo Chang-hoon
Seoul Asan Medical Center

In other words, most of the clinical studies that make up the evidence for domestic clinical guidelines are mostly based on overseas epidemiology and treatment environments, so experts are concerned that they may create guidelines that are far from the ROK's realities.[73]

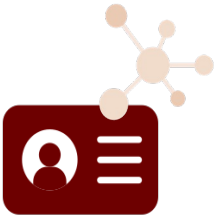
Therefore, before developing tailored and context-appropriate clinical guidelines, including radioligand therapy, sufficient evidence-based data must be produced, and efforts should be made to promote the treatment through active communication, such as the publication of a white paper by the KSMO to establish formal, systematic, and detailed guidelines.[74]

However, since the indications of radioligand therapy and patients subject to benefits are managed within the drug product approval and national reimbursement standards framework approved by MFDS, the criteria for physicians' referrals are generally set. Due to the nature of the ROK's nationalized healthcare system, MFDS and HIRA guidelines have a significant impact on referrals, as physicians' more actively prescribe drugs with formal approval and reimbursements in place.[75] According to these standards, radioligand therapies for NETs are only permitted and/or reimbursed for the progress of non-restrictive and highly differentiated somatostatin receptors and/or for third- or later line treatment of metastatic gastrointestinal NETs, and fourth- or later line treatment of adult patients with pancreatic NETs, and thus radioligand therapy is usually recommended for patients who meet these reimbursement conditions.[14 75 79]

"Securing the level 1 data within Korean-context for rare cancer such as NETs is the most challenging [aspect]. Currently led by Soul Medical Asan Hospital, the ROK's 6 major hospitals are conducting a cohort study and collecting real-world data on patient numbers, survival rate, etc. "

Dr. Yoo Chang-hoon
Seoul Asan Medical Center

For reference, the recommendation, prescription, and treatment process of radioligand therapy in the ROK proceeds as follows:[76-78] First, Ga-68 DOTATOC PET/CT imaging is conducted for eligibility assessment by selecting patients from regional hospital tumor endoscopy or outpatient nuclear medicine departments. The results of the imaging are read by the department of nuclear medicine to check eligibility, and then eligible patients are recommended to undergo treatment. If the patient consents to proceed with the treatment, the hospital orders the treatment necessary for radioligand therapy and simultaneously schedules the treatment for outpatient or hospitalization depending on the facilities installed in the given hospital. Treatment is usually conducted in or out of the hospital for two days and one night. In the case of hospitalization, registration for hospitalization is conducted in the afternoon of the first day, and radioligand therapy is conducted on the second day. Once the radioligand therapy is done, it continues to the treatment with a gamma camera. Following a second DOTATOC imaging, discharge proceeds. Even after discharge, the side effects and effects of treatment are continuously evaluated with outpatient treatment, and future treatment plan is developed.[76-78]



Infrastructure & Licensing

In the ROK, all radiopharmaceuticals needed for radioligand therapy depend on imports.[80] Radiopharmaceuticals refer to drugs used for the purpose of diagnosis and treatment diseases manufactured containing radioisotopes.[81] There are two main types of radiopharmaceuticals; those used for diagnosis and those used for treatment. Unlike conventional drugs radiopharmaceuticals have a half-life, and an eventually lose all radioactivity (and thus effectiveness), radiopharmaceuticals cannot be stored prior to prescription.[82] For example, the half-life of Ga-68 (gallium), a radioisotope for diagnosing NETs, is 68 minutes, and the half-life of Lu-177 (lutetium), a radioisotope for treatment is 6.71 days, all of which are rather short. Because of this, the entire process of assessing needs, manufacturing, activation, and prescription must take place relatively quickly.[82] In the ROK, a Ga-68 generator for imaging is imported and supplied mainly to manufacturers of commercial radiopharmaceuticals located in large university hospitals, and radiopharmaceuticals for treatment of NETs are imported in the form of finished products, which takes an average of two weeks just for air freight shipping due to the ROK's geographical distance from major radiopharmaceutical manufacturing locales.[83] [84]

In this context, radiopharmaceuticals are dependent on imports, geopolitical factors have a decisive impact on the treatment of patients, unlike standard drugs supplied through a typical drug transport system.[85] For example, in the aftermath of the Russia-Ukraine war, radiopharmaceuticals imported from Europe did not arrive in the ROK within an appropriate timeframe considering half-life, making it impossible to use them for treatment, which in turn required all patients' treatment schedules to be changed.[83] Therefore, for radioligand therapy to be prescribed to more indications in the future and to be actively used for the treatment of patients, it is essential to expand the domestic supply infrastructure for radioisotopes.

"There are a rising number of domestic companies treating radiopharmaceuticals in the ROK, but it is not easy to build out GMP (Good Manufacturing Practice) facilities for clinical testing on their own. To improve this situation and secure domestic capacity in developing radiopharmaceuticals, the Korean government is currently investing a lot of effort and resources."

Dr. Kang Keon-wook
Seoul National University Hospital

Recently, the the ROK government has been working with a number of hospitals to set up medical radioisotopes production capacity. In particular, the Korea Atomic Energy Research Institute (KAERI) and the Korea Institute of Radiological & Medical Sciences (KIRAMS) are preparing to produce radioisotopes themselves. In 2020, KAERI succeeded in producing Lutetium-177 (Lu-177) using indirect production methods and supplied it to seven major domestic institutions for research.[87] In 2022, it developed a method to produce and supply Lu-177 only with pure domestic technology. KAERI aims to produce one to two curies (Ci) in 2023 to first meet domestic research application demand.[88] Though it is as yet impossible to produce industrial radioisotopes using existing infrastructure, MSIT, KAERI, and the Busan Metropolitan Government are currently building a new reactor in the Gijang region, which is scheduled to be completed and commissioned by 2026, and be operational by 2027.[89] In addition, some hospitals in the ROK are planning to try to produce their own radioisotope Ga-68 (via cyclotron) in-house for imaging applications within this year.[90] For various attempts to produce radioisotopes in the ROK, dynamic and ongoing interest and support from various policy stakeholders is needed.

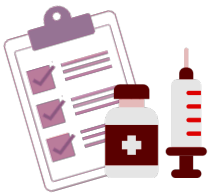
Standards for issuing licenses for radioisotope handling should be re-evaluated and physicians should be supported in applying for them to ensure there is adequate workforce. In the imaging or treatment process of involving radioisotopes in domestic hospitals, at least one holder of radioisotope handler license or Professional Engineer Radiation Management personnel must be present.[91] These licenses are classified into general licenses, special licenses, and supervisor licenses, of which only medical license holders can take a special license test. This includes four subjects: study on either medical science or dentistry; radioisotope and radiation protection; human body-related radioactive substance handling technology; and nuclear-related laws.

However, the difficulty of the license test is quite high - with only a mere 10% of applicants passing. Further, the passing rate of special licenses that nuclear medicine physicians or radiation oncologists will take is also only 10%.[93] The notorious difficulty and the content of questions - often far from the reality of treatment - are also cited as reasons why the application rate for nuclear medicine physicians remains at 10%, and the number of licensed professionals is also shrinking.[94-96] This difficulty in obtaining a license is expected to eventually lead to a workforce shortage, and as such a major obstacle to effectively treating more patients in the future.

"I think this [difficulty in getting a license] is quite a serious and important issue that all nuclear medicine physicians and radiation oncologists are impacted by. We have to talk about this in detail and talk about how we can make change in relevant policies."

Dr. Chung Weon-kuu
Kyung Hee University Hospital at Gangdong

Experts say that the current workforce level can respond to NETs, a rare disease, but if the indication and treatment scope is expanded to prostate cancer (of which prevalence rate is 234.5 per 100,000 and 16,000 per year),[27 28] current workforce capacity will fail to meet the growing demand for radioligand therapy.[97-99] By managing the workforce expertise through appropriate training and education rather than excessively difficult examinations, it will aid securing the proper scale of manpower to response to increasing need for radioligand therapy.[93]



Product approval process

Currently, generalized regulations relevant to product approval of drugs do not reflect the characteristics of radiopharmaceuticals, creating discrepancies. For example, under the drug product approval procedure conducted by MFDS, even if the same drug is used, it must be approved as an individual item for each manufacturer if the manufacturing plant is different;[100 101] this is intended to ensure quality control of general prescription drugs. However, this same requirement also applies *de facto* to radiopharmaceuticals, which must be manufactured and prescribed at manufacturing plants on-site at hospitals due to their extremely short half-life. This is expected to be a major barrier for future prospects when hospitals want to smoothly conduct on-site imaging or treatment with radiopharmaceuticals, including radioligand therapy.[102 103] This issue compounds for regional hospitals in proportion to distance from the capitol or other major urban centers and is a systematic impediment to large-scale expansion of radioligand therapy in the ROK.[103 104]

Currently, Ga-68 is a radiopharmaceutical used in PET scans for people with NETs that is registered in the official compendium and is reported to the public health center as hospital pharmacy formulations, not approved by the MFDS.[82] **This renders case-by-case product approval unnecessary but excludes Ga-86 from insurance reimbursement eligibility.[102 105]** While in the case of imaging procedures using Ga-68, the fee for service is reimbursed while the drug itself is not included, which compels patients to take on the financial burden themselves, even at the diagnosis stage.[106 107]

"Korea's product approval process should include a separate process for radiopharmaceuticals, reflecting their unique characteristics such as half-life and radiation emission."

Choi Young-eun
Korean Orphan & Essential Drug Center

This highlights the need for relevant government stakeholders to take into account procedural and administration costs in order to maximize cost feasibility for medical facilities, and thus ultimately patient access. To resolve this complicated issue, experts advise including the drug cost of Ga-68, which is currently non-reimbursed, in the increased fee for service.[106] [108]

Financial support

National reimbursement standards for radioligand therapy should be expanded to ensure benefits for more patients. As mentioned earlier, non-Hodgkin's lymphoma and some NETs are currently indications eligible for treatment with radioligand therapy in the ROK,[13] [14] but not all patients with these indications are reimbursed for the treatment. First, non-Hodgkin's lymphoma patients can be prescribed radioligand therapy treatments because they are approved in the ROK,[13] but are not registered for reimbursement due to their lack of clear cost-effectiveness compared to alternative drugs in past reviews.[20] [25] This is considered one of the major reasons why radioligand therapy cannot become widespread for the treatment of lymphoma. On the other hand, in the case of treatments with NETs as indications, both the product approval and reimbursement registration process have been successful, and the patient cost burden is only 5% of the total cost.[109]

However, a closer look at these benefits reveals that there are many restrictions on the criteria such as the patient's age, location of tumor expression, and lines of treatments. Currently, patients with NETs that are eligible for insurance benefits when receiving radioligand therapy are the third- or higher line treatment of adult patients with gastrointestinal NETs and the fourth- or higher line treatment of adult patients with pancreatic NETs.[79] The administration of radioligand therapy for the first- and second line treatments in the ROK is considered to be a case exceeding the permitted use limits. If the patient bears the full cost as non-reimbursement, it is considered as arbitrary uninsured medical benefits and is thus not permitted in principle in the ROK.[108] [110] In other words, the domestic health insurance system technically allows radioligand treatment only after the second- or third line of treatments performed in advance.[106]

"During the time when the standards of reimbursement for radioligand therapy were set, patients were not happy as their realities were not fully reflected and their voice was not heard in the end. As a result, only 10% of the patients in patient associations were eligible for treatment reimbursement."

Hwang Won-jae
Korean Association of Neuroendocrine Tumor

In addition, reimbursement is not available even if patients' somatostatin levels are high, when the location of the tumor is expressed in the lungs, thymus, or liver. This makes degree of access to radioligand therapy very low even for patients with lung, thymus, or liver-derived NETs with otherwise sufficient eligibility for treatment.[106] Although current conditions are highly limited to start the treatment early, several clinical studies on the first-line radioligand therapy are in the progress or at the completed stage,[106 111 112] which would pioneer the way to regulatory amendment. To guarantee treatment benefits for more patients, there is a need to revise these standards.[51 52]

The non-reimbursement standard for radioligand therapy, which is regulated together within the national reimbursement standard, should also be amended. In the case of NETs, reimbursements apply only up to four times (i.e., four rounds of radioligand therapy treatment), even if they meet the additional criteria such as age, tumor expression position, and lines of treatment. Two additional lines of treatment are allowed by law but must be fully paid by patients. In this scenario the two additional lines are only permitted if the cancer does not grow and remains dormant for one and a half years after the first line of treatment, and then the disease progresses and requires treatment. In other words, the current standard in national health insurance not only stipulates the scope of reimbursement, but also regulates the non-reimbursement scope. If a patient's cancer fails to meet these criteria and consistently grows, even other therapies or prescriptions that are not covered by insurance are not permitted.[79]

Thus, it is important for patients with NETs to have access to expanded insurance benefits coverage standards for treatment, while simultaneously having access to treatments not covered by insurance yet still permitted by law.[51 52 106] Radioligand therapy expert consensus is that additional treatment can be considered for up to eight rounds of treatment based on the clinical judgment.[99] This, combined with the phenomenon of Korean patients frequently travelling abroad to Germany, India, China, and Malaysia because even non-reimbursed radioligand therapy treatments are unavailable domestically in the ROK, reinforces the necessity of amending insurance coverage standards for radioligand therapy.[52 106]

Currently, nuclear medicine physicians are not included in the drafting and review process of insurance coverage standards for radioligand therapies. In the ROK, the refund system for drugs is largely divided into general drugs and cancer drugs, and radioligand therapies are classified as cancer drugs.[113 114] The Cancer Assessment Committee of the HIRA reviews the medical feasibility of the drug, treatment costs of alternative drugs, and financial impact before setting the standards for drugs used in cancer treatment.[114 115]

"In order to implement an appropriate reimbursement criterion for radioligand therapy, nuclear medicine physicians need to be included on the relevant Cancer Assessment Committee."

Lee Ug
Lee & Ko

The committee consists of 42 cancer experts, with the largest number of clinical experts in hematologic oncology among the committee members, and other clinical experts in each specialized field including surgery, obstetrics, urology, and digestive medicine.[86 116] However, among them, nuclear medicine physicians, who are arguably the most relevant experts in the field of radioligand therapy, are currently not included. For accurate and efficient deliberation of radioligand therapies, it is important for nuclear medicine physicians, who are medical experts in radioligand therapy, to participate in the deliberation process.

Above all, in order to smoothly prescribe and expand radioligand therapy, it is necessary to increase the fee for service by healthcare professionals. While the fee for service is the biggest current obstacle to the expansion of radioligand therapy, it is also considered as a catalyst for future treatment expansion.[45 58 117 118] According to the criteria set by the OECD report, the ROK lies somewhere in between the private model and the public contract model.[119] In other words, it can be said that the government guarantees more medical expenses by public insurance based on the private medical supply system.[120] Therefore, technically, for domestic hospitals that can pursue profit, fee for service is equivalent to hospital profit and if this is low, loss occurs on costs no matter the cost of the given drug or treatment, and radioligand therapy in the ROK is subject to precisely this scenario.

"Unlike how other countries set up radioligand therapy's fee for service compatibility, ROK's low fee for service functions as a major barrier for expansion [of the treatment]. On the other hand, adjusting the fee for service could facilitate expansion of radioligand therapy in the ROK, as it would be a motivation for setting up RLT treatment facilities from a hospital profitability angle as well"

Dr. Hyun Seung-hyup
Samsung Medical Center

Radioligand therapy fundamentally requires a large facility such as a hospital's PET/CT and shielding room to be used by a single patient for a long period of time, but the fee for service is set at less than 100,000 won (Approx. $75), the same as injection.[45 117] Therefore, a total of seven hospitals, including six hospitals in the Seoul metropolitan area that conduct radioligand therapy in the ROK and one regional hospital that recently began treatment, lose money as they treat patients, but continue providing treatment for public interest.[58 121]

In order to ensure sustainability over the long-term however, an increase in the fee for service of radioligand therapy is necessary. If this increase occurs, the sustainability factor for nuclear medicine or oncology departments in charge of treatment in hospitals where radioligand therapy is performed will be strengthened, and investment in facilities (outpatient injection rooms or oncology rooms) will be made to enable more treatment cases.[117 118] Additionally, if facilities that enable the expansion of radioligand therapy in hospitals are expanded, a desirable place for oncology and nuclear medical staff to actively express opinions on the treatment will also be secured, which will ultimately improve the quality of life of a greater number of patients.

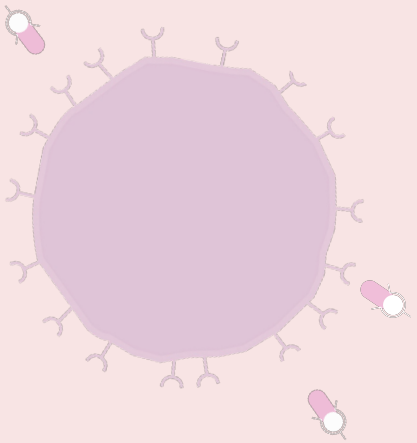
Conclusion

Currently, radioligand therapy differs in their prescriptions and perceptions depending on permitted indications, but in general, patients, physicians, and policymakers are less aware of the treatment. Although radioligand therapy approved by the MFDS as indications for some NETs are limited, NET patients and related medical staff are relatively aware of radioligand therapy, since it is reimbursed. On the other hand, radioligand therapy with non-Hodgkin's lymphoma as an indication were introduced in the ROK long ago, but they have low awareness due to various reasons such as failure to register for reimbursement. In the case of NETs, which are the most active indicators of radioligand therapy in the ROK, the quality of domestic services necessary to provide the treatment, that is, the size of treatable medical staff or medical devices capable of imaging and diagnosis, is sufficient as of now. However, in the future, if indications are expanded, more manpower and infrastructure construction are essential.

Currently, domestic clinical guidelines for indications that can be treated with radioligand therapy, namely NETs, have not yet been developed, and of course, the evidence and data necessary for its development are not sufficient. In addition, the government and some major hospitals are striving to produced radioisotopes on their own, but at present, all radiopharmaceuticals necessary for the radioligand therapy depend on imports. In addition, radioligand therapy, or radiopharmaceutical therapy, have distinctly different characteristics from general medicines and must be regulated differently, but they are currently inefficiently managed under the same regulations. Due to the restrictive reimbursement standards that do not properly reflect the treatment environment and the low fee for service, benefits are not being provided to as many patients as would otherwise be possible.

In conclusion, radioligand therapy has not yet been properly integrated into the existing domestic medical and healthcare systems, and action from numerous stakeholders is needed to continue to make related improvements toward a more desirable direction. Research around radioligand therapy is expected to continue to develop rapidly, and research to expand existing indications is also actively underway, so the treatment is expected to be possible soon. And again, the ROK government properly integrate advanced radioligand therapy into the existing local healthcare system.

Therefore, the ROK government should preemptively improve the deficiencies through analysis of various items necessary to expand radioligand therapy, discover opportunities for development, and continue to lead appropriate planning and policy amendments. Further, in this process, all related stakeholders should actively cooperate and lead consensus to ensure that the therapy is made more readily available to people who could most benefit from it.



Glossary

This glossary provides definitions of terms as they are used in this report. They are derived from existing sources and adapted for the purposes of this project.

Alternative drugs are the drugs with a clinically equivalent position in the product approval and reimbursement standards, based on textbooks, clinical guidelines, and clinical research papers.

Arbitrary uninsured medical benefit is an act that is not currently recognized as a benefit under the *Health Insurance Act* but medical institutes carry out and charge the patients for the treatment with the patient's consent, based on the patient's request or medical need.

Clinical guidelines refer to statements systematically developed to help doctors and patients make treatment-related decisions in specific scenarios.

Clinical indication is a health condition that could benefit from a specific test, therapy or procedure. If a therapy has been established and approved by regulatory bodies, the therapy is said to be approved for a specific indication.

Computed tomography (CT) scans use X-rays to create images of the body at different angles. A computer uses these images to develop a 3D image. X-rays help identify changes to bones and tissue caused by cancer or other disease.

Eligibility assessment is used to evaluate whether radioligand therapy is a suitable treatment option for a particular individual based on the outcome of specific, often imaging, tests.

Fee for service is total amount that medical institutes receive from patients and the National Health Insurance Service for the service covered by National Health Insurance.

Gamma camera is one of the parts of cancer diagnosis and for the monitoring of treatment.

Ga-68 DOTATOC PET/CT scan captures neuroendocrine tumors (NETs) that overexpress somatostatin receptors and show where the tumors are in the body. It is a tool for the care of low or intermediate grade neuroendocrine tumors, primarily for making treatment decisions with early detection of small lesions that impact treatment plans.

Governance refers to a range of policies, standards and ways of working that directly impact the availability, accessibility, and standards of delivery for any therapy, ultimately influencing health outcomes.

Incidence is the rate of new cases or events over a specified period for the population at risk for the event. It can be specified as person-years.

Ligand is a small molecule that selectively binds to a specific different molecule. Examples are a hormone binding to a receptor on a cell, or an antibody binding to an antigen.

Lymphoma is a type of blood cancer that affects the lymphatic system. Lymphoma develops when white blood cells grow uncontrollably. There are over 60 types of lymphoma, with different treatment requirements.

Metastatic castration-resistant prostate cancer (mCRPC) is an advanced type of prostate cancer that has spread to the bone and has become resistant to hormonal cancer therapy.

Neuroendocrine tumors (NETs) are a group of cancers which occur in neuroendocrine cells. NETs arise from cells of the hormonal and nervous system that can develop in many different organs of the body.

Nuclear medicine is a medical discipline that involves the application of radioactive substances to assess bodily functions and diagnose and treat disease.

Prevalence is the proportion of a population who have a specific characteristic in a given time period. It may be reported as a percentage (5%, or 5 people out of 100), or as the number of cases per 10,000 or 100,000 people.

Positron-emission tomography (PET) scanners use radioactive tracers to produce 3D images of the inside of the body. The scan shows how organs and tissues function and can also provide evidence of the presence or absence of cancer.

Radiation is the emission of energy as electromagnetic waves or subatomic particles. This energy can be emitted by radionuclides and used to diagnose or treat disease.

Radioimmunotherapy is a treatment that uses a cancer-targeting antibody to deliver a radioisotope directly to cancer cells to kill them. It is used to treat certain types of lymphoma.

Radioisotope (or radionuclide) is an unstable form of a chemical element that emits radiation as it breaks down to a stable form. Radioisotopes may occur naturally or be made in a laboratory. Different radioisotopes have different properties and applications – for example, different radioisotopes would be used for diagnosing or treating a cancer.

Radioligand is a cancer-targeting molecule, or ligand, attached to a radionuclide. By choosing different radionuclides to attach to the same type of ligand, the process can be tailored to either diagnose or treat different types of cancer.

Regulation defines why and when a healthcare intervention should be provided and how it can be delivered safely to patients, including the appropriate rules and safeguards that need to be in place.

Radiopharmaceuticals are a group of pharmaceutical drugs containing radioactive isotopes. They can be used as diagnostic and therapeutic agents.

Targeted therapy is a category of cancer treatment that exploits differences between healthy and cancerous cells. It can be used to target a treatment to cancerous cells with minimal effect on healthy cells.

Appendix

TABLE 1. Radioligand therapies licensed in the ROK

Indication	Description of indication	Therapy licensed by MFDS for use in clinical practice in the ROK	National reimbursement[1] (reimbursement date)
Follicular lymphoma	The most common type of slow-growing non-Hodgkin's lymphoma that develops from B cells. The abnormal B cells typically form in clumps inside lymph nodes	Zevalin kit inj (Ibritumomab Tiuxetan) (25/01/08)	Non-reimbursement
Gastroenteropancreatic neuroendocrinetumors, GEP-NET	A rare type of neuroendocrine tumor that can form in the pancreas or in other parts of the gastrointestinal tract, including the stomach, small intestine, colon, rectum, and appendix	Lutetium-177 oxodotreotide (09/07/20)	reimbursement (01/03/22)

❊ In general, after the MFDS product approval, the HIRA evaluates the financial feasibility and reimbursement appropriateness of the drug. After that, the drug is listed as reimbursement through negotiations with NHIS.

TABLE 2. Clinical indications for radioligand therapy in international/domestic phase II and III clinical trials

Indication in phase II clinical trials[a]	Indication in phase III clinical trials[b]	Description
Carcinoid heart disease[122]		Carcinoid heart disease is a rare condition that is related to raised levels of peptides and hormones produced by neuroendocrine cancer cells. It usually affects the right-sided heart valves and leads to right heart failure
Central nervous system cancer[33,34,123c]		Central nervous system cancer begins in the brain or the spinal cord. It encompasses over 100 distinct tumor types
Lymphoma sub-types including relapsed indolent non-Hodgkin's lymphoma and relapsed/refractory follicular lymphoma[29]		Lymphoma is a type of cancer that develops in the lymphatic system
Neuroendocrine neoplasm sub-types including paraganglioma, pheochromocytoma and neuroendocrine breast tumours, among many others[30, 124, 125, 126c]	Gastroenteropancreatic neuroendocrine neoplasms[111]	Neuroendocrine tumors arise from cells of the hormonal and nervous system that can develop in many different organs of the body
Meningioma[33,123c,127]		A meningioma is a tumor that grows from the tissues that line the brain
Metastatic breast cancer[35]		Metastatic breast cancer is breast cancer that has spread to other parts of the body
Metastatic castration-resistant prostate cancer[128 129]	Metastatic castration-resistant prostate cancer[130c]	Metastatic castration-resistant prostate cancer is a cancer that has spread beyond the prostate gland and where hormone therapy is no longer effective in stopping or slowing the disease
Peritoneal solid tumours[131]		Peritoneal solid tumors are a rare type of cancer that are found in the lining tissue of the abdomen

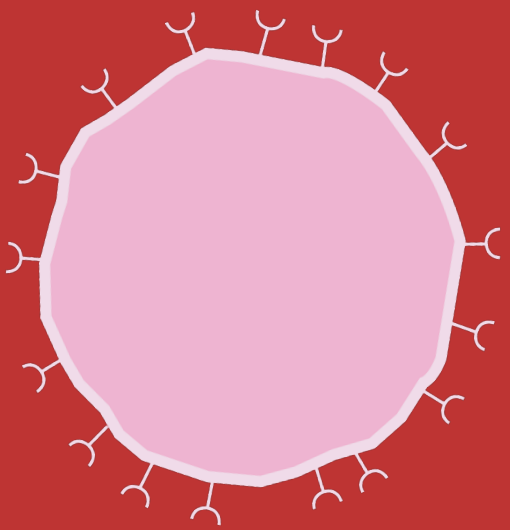
a. Phase II at the time of publication (2023).
b. Phase III at the time of publication (2023).
c. Study closed at the time of publication (2023).

References

1. Jadvar H. 2017. Targeted Radionuclide Therapy: An Evolution Toward Precision Cancer Treatment. AJR Am J Roentgenol 209(2): 277-88
2. Fahey F, Zukotynski K, Capala J, et al. 2014. Targeted radionuclide therapy: proceedings of a joint workshop hosted by the National Cancer Institute and the Society of Nuclear Medicine and Molecular Imaging. J Nucl Med 55(2): 337-48
3. Strosberg J, El-Haddad G, Wolin E, et al. 2017. Phase 3 Trial of (177)Lu-Dotatate for Midgut Neuroendocrine Tumors. N Engl J Med 376(2): 125-35
4. Marinova M, Mücke M, Mahlberg L, et al. 2018. Improving quality of life in patients with pancreatic neuroendocrine tumor following peptide receptor radionuclide therapy assessed by EORTC QLQ-C30. Eur J Nucl Med Mol Imaging 45(1): 38-46
5. Cheson BD. 2003. Radioimmunotherapy of non-Hodgkin lymphomas. Blood 101(2): 391-98
6. Kolstad A, Madsbu U, Beasley M, et al. 2018. LYMRIT 37-01: A phase I/II study of 177lu-lilotomab satetraxetan (Betalutin®) antibody-radionuclide-conjugate (ARC) for the treatment of relapsed non-Hodgkin's lymphoma (NHL) — analysis with 6-month follow-up. Blood: 10.1182/blood-2018-99-110555
7. Witzig TE, Gordon LI, Cabanillas F, et al. 2002. Randomized controlled trial of yttrium-90-labeled ibritumomab tiuxetan radioimmunotherapy versus rituximab immunotherapy for patients with relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkin's lymphoma. J Clin Oncol 20(10): 2453-63
8. Katona BW, et al. 2017. Pancreas 46(9): 1121-26
9. Halfdanarson JSS, et al. 2021. Onco Targets Ther 13: 3545-55
10. Sartor O, de Bono J, Chi KN, et al. 2021. Lutetium-177– PSMA-617 for Metastatic Castration-Resistant Prostate Cancer. N Engl J Med: 10.1056/NEJMoa2107322
11. Herrmann K, Schwaiger M, Lewis JS, et al. 2020. Radiotheranostics: a roadmap for future development. Lancet Oncol 21(3): e146-e56
12. Lim SM, Kang HJ, Kim BI, et al. 2017.난치암 환자들을 위한 방사성의약품 치료. Seoul: 한국원자력의학원
13. Ministry of Food and Drug Safety (MFDS). 의약품통합정보시스템: 제바린키트주사 [Updated 01/07/23]. Available from: https://nedrug.mfds.go.kr/pbp/CCBBB01/getItemDetailCache?cacheSeq=200801091aupdateTs2023-07-10%2017:10:19.0b [Accessed 21/06/23]
14. MFDS. 의약품통합정보시스템: 루타테라주[Updated 07/09/20]. Available from: https://nedrug.mfds.go.kr/pbp/CCBBB01/getItemDetailCache?cacheSeq=202004981aupdateTs2023-07-04%2015:10:24.037624b [Accessed 21/06/23]
15. Ministry of Health and Welfare (MOHW). 2022년 건강보험정책심의위원회 개최 보도자료. Available from: http://www.mohw.go.kr/react/al/sal0301vw.jsp?PAR_MENU_ID=04&MENU_ID=0403&CONT_SEQ=370391&page=38 [Accessed 21/06/23]
16. Health Korea News. 2023. 암세포 정밀 타격 방사성 리간드 치료제 개발 경쟁 후끈. Available from: https://www.hkn24.com/news/articleView.html?idxno=332656
17. Dental Today. 2022. 우리나라 고가 의료장비 얼마나 될까. Available from: https://www.dttoday.com/news/articleView.html?idxno=90521
18. MOHW. 2022. 제 5차 국민보건의료실태조사 결과발표 보도자료. Available from: https://www.korea.kr/docViewer/skin/doc.html?fn=196862337&rs=/docViewer/result/2022.07/14/196862337
19. Seo GH, Kim SW, Chung JH. 2013. Incidence & prevalence of hyperthyroidism and preference for therapeutic modalities in Korea. J Korean Thyroid Assoc. 6(1): 56-63
20. Doctors News. 2017. 비호지킨 림프종 치료제 '제바린키트' 급여 실패. Available from: https://www.doctorsnews.co.kr/news/articleView.html?idxno=120574
21. Jeong SY. 2019. Updates of Radioiodine Treatment for Graves' Disease. Int J Thyroidol. 12(2): 85-90.
22. Medical Times. 2023. 플루빅토, 식약처 '글로벌혁신제품 신속심사' 지정. Available from: https://www.medicaltimes.com/Main/News/NewsView.html?ID=1154039
23. Pharm E Daily. 2023. [2023 유망바이오 섹터 톱10] 암치료 새강자, 방사성 의약품 ⑩. Available from: https://pharm.edaily.co.kr/news/read?newsId=01872886635481656
24. Health Focus. 2021. 획기적인 전립선암 치료법, 국산화 성공하나. Available from: http://m.healthfocus.co.kr/news/articleView.html?idxno=100756
25. Health Insurance Review & Assessment Service (HIRA). 2007. 암질환 사용약제 및 요법 FAQ. Available from: https://www.hira.or.kr/bbsDummy.do?pgmid=HIRAA03002308000&brdScnBltNo=4&brdBltNo=45584 [Accessed 10/08/23]
26. Hit News. 2023. 글로벌 혁신제품 신속심사 8건 지정…허가 연결은 '없음'. Available from: http://www.hitnews.co.kr/news/articleView.html?idxno=46418
27. National Cancer Information Center (NCIC). 2023. 암종별 암유병률. [Updated 06/01/23] Available from: https://www.cancer.go.kr/lay1/S1T654C656/contents.do [Accessed 10/08/23]
28. NCIC. 2023. 암종별 발생 현황. [Updated 05/01/23] Available from: https://www.cancer.go.kr/lay1/S1T639C641/contents.do [Accessed 10/08/23]
29. ClinicalTrials.gov. A Phase I/II Study of Betalutin for Treatment of Relapsed Non-Hodgkin Lymphoma (LYMRIT-37-01). [Updated 14/09/22]. Available from: https://clinicaltrials.gov/ct2/show/NCT01796171 [Accessed 24/06/23]
30. ClinicalTrials.gov. Study to Evaluate Safety and Dosimetry of Lutathera in Adolescent Patients With GEP-NETs and PPGLs. [Updated 08/06/23]. Available from: https://clinicaltrials.gov/ct2/show/NCT04711135 [Accessed 24/06/23]
31. ClinicalTrials.gov. VSV-hIFNbeta-NIS with or without ruxolitinib phosphate in treating patients with relapsed or refractory multiple myeloma, acute myeloid leukemia, or T-cell lymphoma. [Updated 02/08/23]. Available from: https://clinicaltrials.gov/ct2/show/NCT03017820 [Accessed 24/06/23]
32. ClinicalTrials.gov. Yttrium-90 labeled anti-CD25 monoclonal antibody combined with BEAM chemotherapy conditioning for the treatment of primary refractory or relapsed Hodgkin lymphoma. [Updated 22/06/23]. Available from: https://clinicaltrials.gov/ct2/show/NCT04871607 [Accessed 24/06/23]
33. ClinicalTrials.gov. 131I-omburtamab Radioimmunotherapy for Neuroblastoma Central Nervous System/ Leptomeningeal Metastases. [Updated 09/03/23]. Available from: https://clinicaltrials.gov/ct2/show/NCT03275402 [Accessed 10/08/23]
34. ClinicalTrials.gov. 131I-Omburtamab, in Recurrent Medulloblastoma and Ependymoma. [Updated 09/03/23]. Available from: https://clinicaltrials.gov/ct2/show/NCT04743661 [Accessed 08/26/21]
35. ClinicalTrials.gov. 177Lu-DOTATATE for the Treatment of Stage IV or Recurrent Breast Cancer. [Updated 11/07/22]. Available from: https://clinicaltrials.gov/study/NCT04529044 [Accessed 24/06/23]

36. ClinicalTrials.gov. A Trial of 177Lu-PSMA617 Theranostic Versus Cabazitaxel in Progressive Metastatic Castration Resistant Prostate Cancer (TheraP). [Updated 09/26/19]. Available from: https://clinicaltrials.gov/ct2/show/NCT03392428 [Accessed 07/02/21]
37. Hit News. 2023. 10년간 미·유럽·일 신약 허가기간 단축… 한국은 증가세. Available from: http://www.hitnews.co.kr/news/articleView.html?idxno=43302
38. Korean Society of Nuclear Medicine (KSNM). 연도별 (2013~2019년) 핵의학 검사통계. Available from: https://www.ksnm.or.kr/stats/bbs/skin/default/download.php?code=notice&number=43
39. Doctors News. 2017. 핵의학회, 신경내분비종양 환자 위한 토론회 제도개선 논의. Available from: https://www.doctorsnews.co.kr/news/articleView.html?idxno=119498
40. Medigate News. 2020. 코로나19로 해외 원정치료 길 막혀..'루타테라' 재난적의료비 지원. Available from: https://m.medigatenews.com/news/1889469901
41. News the Voice. 2020. 루타테라, 정식 허가 뒷전…환자들만 더 아프다. Available from: https://www.newsthevoice.com/news/articleView.html?idxno=11748
42. Medical Times. 2020. 환자단체 루타테라 허가 촉구…식약처 '우선심사' 약속. Available from: https://www.medicaltimes.com/Main/News/NewsView.html?ID=1133626
43. MediPharm Health. 2020. 신경내분비종양 환자 "심사평가원,건강보험 급여결정 빠르게 진행해 달라" Available from: http://www.medipharmhealth.co.kr/news/article.html?no=63912
44. Korean Association of Neuroendocrine Tumor (KANT). Available from: https://cafe.naver.com/neuroendocrinetumor
45. E-Medi Info. 2022. 신경내분비종양, 인식 개선 및 지원 절실. Available from: http://m.kmedinfo.co.kr/news/articleView.html?idxno=74730
46. Kang KW. 2023. GR Korea Written Survey. 14/04/23
47. Medical Observer. 2022. 대한종양내과학회, 신경내분비종양 환자 위한 캠페인 런칭. Available from: http://www.monews.co.kr/news/articleView.html?idxno=310348
48. Korean Society of Medical Oncology (KSMO). 2022. 신경내분비종양 넷터치 캠페인(YouTube). Available from: https://www.youtube.com/watch?v=OojiOb3t36k
49. Asan Medical Center. 2023. 신경내분비종양 환자를 위한 방사성의약품 치료(YouTube). Available from: https://www.youtube.com/watch?v=px1BOXp6pKc
50. Lee U. 2023. GR Korea Written Survey. 14/04/23
51. News the Voice. 2022. 루타테라·벤리스타…"왜 한국만 급여 투여기간 제한하나". Available from: https://www.newsthevoice.com/news/articleView.html?idxno=27526
52. Rapportian. 2022. '루타테라' 급여화됐지만…원정치료 내몰리는 신경내분비종양 환자들. Available from: https://www.rapportian.com/news/articleView.html?idxno=149645
53. Samsung Hospital. 삼성서울병원 신경내분비종양(NET)클리닉. Available from: http://www.samsunghospital.com/home/cancer/carecenter/special/clinicNeuroendocrine.do [Accessed 27/07/23]
54. Hwang WJ. 2023. GR Korea Written Survey. 22/03/23
55. Korean Statistical Information Service (KOSIS). 2023. 요양기관 종별 전문의 인력현황. Available from: https://kosis.kr/statHtml/statHtml.do?orgId=354&tblId=DT_HIRA4K&conn_path=I2 [Accessed 27/07/23]
56. Medical Times. 2022. 핵의학·소아청소년과 지원율 10%대 불명예. Available from: https://www.medicaltimes.com/Main/News/NewsView.html?ID=1151126
57. Yoo CH. 2023. GR Korea Written Survey. 18/03/23
58. Medigate News. 2022. 췌장암 등으로 오인가능 '신경내분비종양', 어떤 치료를 받아야 할까? Available from: https://medigatenews.com/news/4004335697
59. Kang KW. 2023. GR Korea Written Survey. 14/04/23
60. MOHW. 2021. 국가암관리종합계획('21-'25). Available from: https://www.mohw.go.kr/react/gm/sgm0704vw.jsp?PAR_MENU_ID=13&MENU_ID=13040801&page=1&CONT_SEQ=368884&PAR_CONT_SEQ=355750
61. Ministry of Science and ICT (MSIT). 2022. 제3차 방사선진흥계획('22~'26). Available from: https://www.msit.go.kr/publicinfo/view.do?sCode=user&mPid=62&mId=63&publictSeqNo=5&publictListSeqNo=3&formMode=R&referKey=5,3
62. National Science & Technology Information Service (NTIS).방사성동위원소 관련 국가R&D 통합공고. Available from: https://www.ntis.go.kr/rndgate/eg/un/ra/mng.do [Accessed 10/08/23]
63. Hit News. 2022. "신의료기술평가 사전규제 폐지하는 것이 바람직". Available from: http://www.hitnews.co.kr/news/articleView.html?idxno=41208
64. Korean Academy of Medical Sciences (KAMS). 임상진료지침 정보센터: 진료지침의 평가. Available from: https://www.guideline.or.kr/evaluation/sub3.php [Accessed 27/07/23]
65. KAMS. 임상진료지침 정보센터: 진료지침 신규개발. Available from: https://www.guideline.or.kr/evaluation/index.php?sub=1 [Accessed 27/07/23]
66. National Cancer Center (NCC). 국가 암 진료 가이드라인 사업단. 국가 암 진료가이드라인 제정 매뉴얼. Available from: http://www.ko-amguide.com/content/community/post_view.php?bt=3&post_id=103&page=1&bcode= [Accessed 27/07/23]
67. National Comprehensive Cancer Network (NCCN). 2023. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Neuroendocrine and Adrenal Tumors. Plymouth Meeting, PA: NCCN
68. Pavel M, Oberg K, Falconi M, Krenning E.P., Sundin A, Perren A, Berruti A. 2020. Gastroenteropancreatic neuroendocrine neoplasms: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology. 31(7): 844-860
69. Yoo CH. GR Korea Written Survey. 18/03/23
70. Yoo CH, Oh CR, Kim ST, et al. 2021. Systemic Treatment of Advanced Gastroenteropancreatic Neuroendocrine Tumors in Korea: Literature Review and Expert Opinion. Cancer Res Treat. 53(2): 291-300
71. NCIC. 2022. 전립선암 관련 통계. Available from: https://cancer.go.kr/lay1/program/S1T211C218/cancer/view.do?cancer_seq=4949&menu_seq=4954
72. Korean Urological Association (KUA), Korean Urological Oncology Society (KUOS). 2018. 전립선암 치료 진료권고안. Available from: https://www.guideline.or.kr/guide/view.php?number=1078&cate=A
73. KAMS. 임상진료지침 정보센터: 진료지침 신규개발. Available from: https://www.guideline.or.kr/evaluation/index.php?sub=2 [Accessed 13/06/23]
74. Yoo CH. 2023. GR Korea 2nd In-person Interview. 24/05/23
75. Hwang WJ. 2023. GR Korea Written Survey. 22/03/23
76. Kang KW. 2023. GR Korea Written Survey. 14/04/23
77. Hyun SH. 2023. GR Korea Written Survey. 09/04/23
78. Hyun SH. 2023. GR Korea 2nd Written Interview. 13/07/23
79. HIRA. 2022. 암환자에게 처방·투약하는 약제에 대한 요양급여의 적용기준 및 방법에 관한 세부사항 (건강보험심사평가원 공고 제2022-206호). Available from: https://www.hira.or.kr/bbsDummy.do?pgmid=HIRAA030023010000&brdScnBltNo=4&brdBltNo=45614&pageIndex=1&pageIndex2=1
80. Daily Medi. 2020. 한국원자력의학원, 치료용 방사성의약품 국내 보급 본격화 Available from: https://www.dailymedi.com/news/news_view.php?wr_id=853879
81. MFDS. 의약품의 품목허가·신고·심사 규정(식품의약품안전처고시 제2021-90호). Available from: https://www.law.go.kr/LSW//admRulInfoP.do?admRulSeq=2100000206068&chrClsCd=010201#

82. Lee BE. 2016. 방사성의약품 관리. J. Kor. Soc. Health-Syst. Pharm., 33(3): 268-277 Available from: https://www.jkshp.or.kr/journal/view.html?uid=1492&vmd=Full
83. Kang KW. 2023. GR Korea 1st In-person Interview. 16/03/23
84. Kang KW. 2023. GR Korea Written Survey. 14/04/23
85. Deloitte Insights. 2022. 전쟁과 인플레이션, 공급망과 지정학적 위험: 딜로이트 글로벌&중국 수석이코노미스트 지상 대담. Available from: https://www2.deloitte.com/content/dam/Deloitte/kr/Documents/insights/deloitte-korea-review/21/DI-No.21_Chapter01_3.pdf
86. HIRA. 제9기(2021.12.1-2023.11.30) 중증(암)질환심의위원회 위원 명단. Available from: https://www.hira.or.kr/dummy.do?pgmid=HIRAA030051000016 [Accessed 07/29/23]
87. Korea Atomic Energy Research Institute (KAERI). 2020. 국내 최초, 고순도 진단치료용 동위원소 2종 생산. Available from: https://www.kaeri.re.kr/env/board/view?pageNum=5&rowCnt=10&menuId=MENU00326&schType=0&schYear=&schText=&categoryId=&continent=&country=&boardStyle=Image&linkId=8633
88. KAERI. 2022. 꿈의 동위원소 '루테튬-177' 순수 국내기술로 첫 공급. Available from: https://www.kaeri.re.kr/rcus/board/view?pageNum=2&rowCnt=10&menuId=MENU00326&schType=0&schYear=&schText=&categoryId=&continent=&country=&boardStyle=Text&linkId=10559
89. KAERI. 2023. 국민 의료 복지 향상을 위한 '수출용신형연구로' 본격 건설 착수. Available from: https://www.kaeri.re.kr/board/view?pageNum=1&rowCnt=10&menuId=MENU00326&schType=0&schYear=&schText=&categoryId=&continent=&country=&boardStyle=Image&linkId=11060
90. Kang KW. 2023. GR Korea 2nd In-person Interview. 18/05/23
91. Medical Observer. 2013. 방사선 특수 면허 개선돼야. Available from: http://www.monews.co.kr/news/articleView.html?idxno=56027
92. Korea Certified Information (KCI). 방사성동위원소취급자특수면허. Available from: http://www.koci.co.kr/base/m4/menu22.php
93. Youth Doctor. 2022. '꼴찌 반란' 모색하는 핵의학과…"성장 걸맞은 지원을". Available from: http://www.docdocdoc.co.kr/news/articleView.html?idxno=2028937
94. Chung WK. 2023. GR Korea 1st In-person Interview. 16/03/23
95. Chung WK. 2023. GR Korea 2nd In-person Interview. 18/05/23
96. Kang KW. 2023. GR Korea 2nd In-person Interview. 18/05/23
97. Kang KW. 2023. GR Korea Written Survey. 14/04/23
98. Chung WK. 2023. GR Korea Written Survey. 22/03/23
99. Yoo CH. 2023. GR Korea Written Survey. 18/03/23
100. MFDS.2017. 의약품 품목 허가·심사 절차의 이해. Available from: https://www.mfds.go.kr/brd/m_218/view.do?seq=28189 [Accessed 10/08/23]
101. MFDS. 2015. 방사성의약품 품목허가를 위한 안내서. Available from:https://www.mfds.go.kr/brd/m_1060/view.do?seq=12150&srchFr=&srchTo=&srchWord=&srchTp=&itm_seq_1=0&itm_seq_2=0&multi_itm_seq=0&company_cd=&company_nm=&page=106 [Accessed 10/08/23]
102. Kang KW. 2023. GR Korea 1st In-person Interview. 16/03/23
103. Choi YE. 2023. GR Korea 2nd In-person Interview. 18/05/23
104. Choi YE. 2023. GR Korea 1st Written Interview. 22/06/23
105. Kang KW. 2023. GR Korea 2nd In-person Interview. 18/05/23
106. Hwang WJ. 2023. GR Korea Written Survey. 22/03/23
107. Hyun SH. 2023. GR Korea Written Survey. 09/04/23
108. Lee U. 2023. GR Korea 1st Written Interview. 25/06/23
109. Asia Economics. 2022. 다음달부터 '루타테라주' 건보적용…환자부담 440만원으로. Available from: https://www.asiae.co.kr/article/2022022612182489688
110. Lee U. 2023. GR Korea 2nd Written Interview. 14/07/23
111. ClinicalTrials.gov. Study to Evaluate the Efficacy and Safety of Lutathera in Patients With Grade 2 and Grade 3 Advanced GEP-NET (NETTER-2). [Updated 27/07/23]. Available from: https://clinicaltrials.gov/study/NCT03972488 [Accessed 08/08/23]
112. Yakup News. 2022. 루타테라-모두가 만족하는 치료제로 거듭날까? Available from: http://m.yakup.com/news/index.html?mode=view&nid=271365
113. Lee U. 2023. GR Korea Written Survey. 14/04/23
114. HIRA. 2021. 약제 요양급여의 적정성 평가 결과 177Lutetium oxodotreotide 370Mbq/mL (루타테라주, 한국노바티스(주)). [Updated 04/05/22] Available from: https://www.hira.or.kr/bbsDummy.do?brdBltNo=46935&brdScnBltNo=4&pgmid=HIRAA030014040000#none [Accessed 10/08/23]
115. HIRA. 2021. 루타테라주 (한국노바티스(주)) 회의자료. [Updated 04/05/22] Available from: https://www.hira.or.kr/bbsDummy.do?brdBltNo=46935&brdScnBltNo=4&pgmid=HIRAA030014040000#none [Accessed 10/08/23]
116. HIRA. 2022. 중증질환심의위원회 운영규정. Available from: https://www.alio.go.kr/download/rulefiledown.json?fileNo=1578100 [Accessed 10/08/23]
117. Hyun SH. 2023. GR Korea Written Survey. 09/04/23
118. Kang KW. 2023. GR Korea Written Survey. 14/04/23
119. OECD. 2010. Health care systems: efficiency and policy settings. OECD Publishing. Available from: https://doi.org/10.1787/9789264094901-en
120. Choi BH, Kim NS, Kim JH, Lee SI, Jung HS. 2016. 한국 보건의료정책의 현황과 과제 - 전문가에게 길을 묻다. Health and welfare policy forum [Internet]. 2016(12):4–26. Available from: https://doi.org/10.23062/2016.12.2
121. Chonnam National University Hospital (CNUH). 2023. 화순전남대병원, 신경내분비종양 루타테라 치료 지방 최초 도입. Available from: https://www.cnuh.com/story/people.cs?act=view&articleId=37467
122. ClinicalTrials.gov. Carcinoid Heart Disease and Peptide Receptor Radiotargetted Therapy (CHARRT). [Updated 08/04/20]. Available from: https://www.clinicaltrials.gov/study/NCT04039516?intr=Lutathera&rank=4 [Accessed 10/08/23]
123. ClinicalTrials.gov. Iodine I 131 Monoclonal Antibody 3F8 in Treating Patients With Central Nervous System Cancer or Leptomeningeal Cancer. [Updated 02/02/23]. Available from: https://clinicaltrials.gov/study/NCT00445965 [Accessed 24/06/23]
124. ClinicalTrials.gov. Peptide Receptor Radionuclide Therapy in the Treatment of Advanced, Non-resectable and/or Symptomatic Tumors With SSTR Overexpression (POLNETS_PRRT). [Updated 04/01/20]. Available from: https://clinicaltrials.gov/study/NCT04029428 [Accessed 24/06/23]
125. ClinicalTrials.gov. Lu-177-DOTATATE (Lutathera) in Therapy of Inoperable Pheochromocytoma/Paraganglioma. [Updated 07/08/23]. Available from: https://clinicaltrials.gov/study/NCT03206060 [Accessed 10/08/23]
126. ClinicalTrials.gov. Phase-II Study of Lu177DOTATOC in Adults With STTR(+)Pulmonary, Pheochromocytoma, Paraganglioma, Unknown Primary, Thymus NETs (PUTNET), or Any Other Non-.GEP-NET. (PUTNET). [Updated 10/03/23]. Available from: https://clinicaltrials.gov/study/NCT04276597 [Accessed 24/06/23]
127. ClinicalTrials.gov. Phase II Study of 177Lu-DOTATATE Radionuclide in Adults With Progressive or High-risk Meningioma. [Updated 04/08/23]. Available from: https://clinicaltrials.gov/study/NCT03971461 [Accessed 10/08/23]
128. ClinicalTrials.gov. 177Lu-PSMA-I & T PSMA Radioligand Therapy in Metastatic Castration-Resistant Prostate Cancer. [Updated 06/12/19] Available from: https://clinicaltrials.gov/study/NCT04188587 [Accessed 24/06/23]
129. MFDS. A phase 1/2 clinical trial to evaluate the safety, tolerability, dosimetry and anti-tumor activity of Ga-68-NGUL/Lu-177-DGUL in patients with metastatic castration-resistant prostate cancer (mCRPC) refractory to standard therapy. [Updated 18/11/22] Available from: http://surl.li/jymfy [Accessed 24/06/23]
130. ClinicalTrials.gov. Study of 177Lu-PSMA-617 In Metastatic Castrate-Resistant Prostate Cancer (VISION). [Updated 11/08/22]. Available from: https://clinicaltrials.gov/study/NCT03511664 [Accessed 24/06/23]
131. ClinicalTrials.gov. A Study of the Drug I131-Omburtamab in People With Desmoplastic Small Round Cell Tumors and Other Solid Tumors in the Peritoneum. [Updated 08/12/22]. Available from: https://clinicaltrials.gov/study/NCT04022213 [Accessed 24/06/23]



Korea