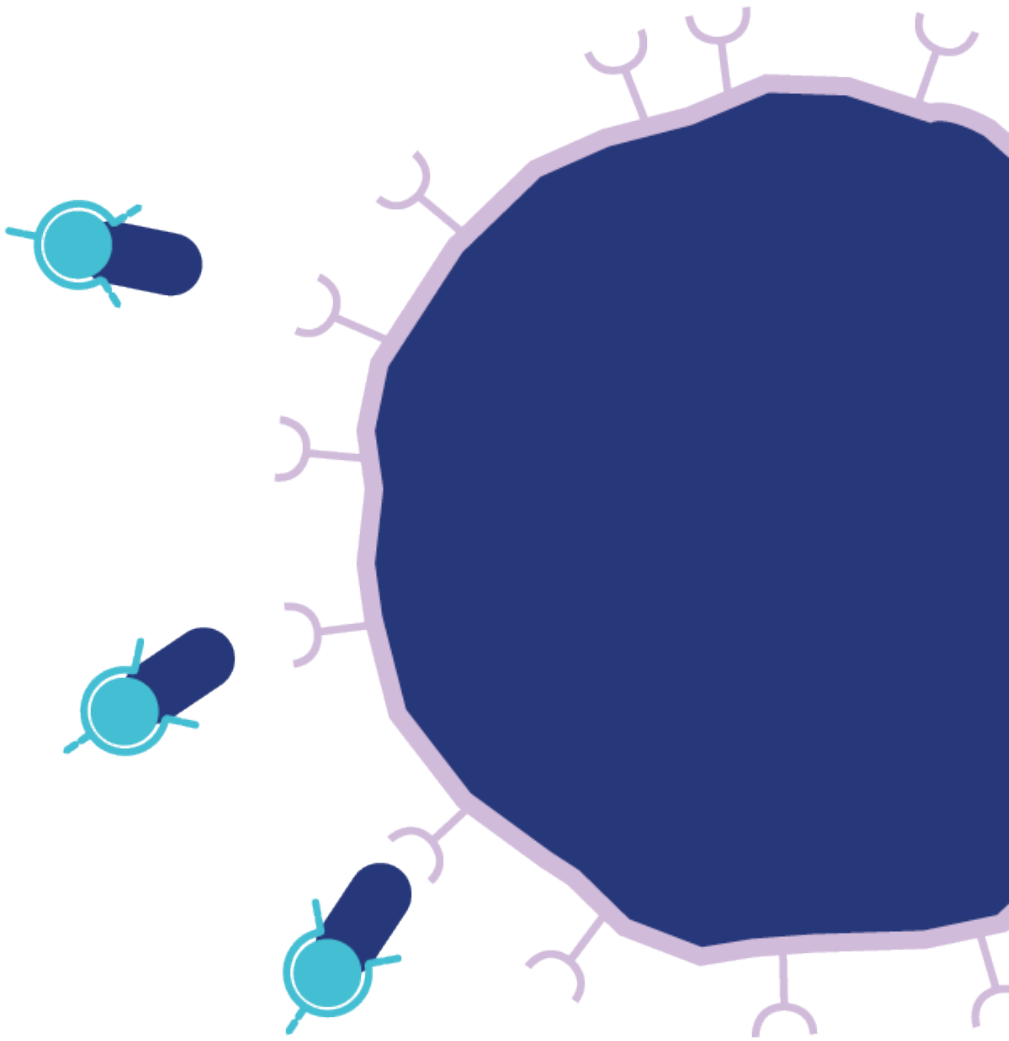

The Health Policy Partnership

[research, people, action]

Radioligand Therapy Readiness Assessment Framework: US

November 2021

This framework has been developed by The Health Policy Partnership as part of an ongoing project. US materials were developed in collaboration with Avalere Health and a US Expert Advisory Group, who had full editorial control. The project is supported with funding from Advanced Accelerator Applications, a Novartis Company, with additional support from Nordic Nanovector.

About the radioligand therapy readiness assessment project

This document has been developed by The Health Policy Partnership, in collaboration with Avalere Health and a US 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 US. It is supported by other resources, such as working papers, a summary report and a policy action blueprint on health system readiness for radioligand therapy in the US. For more information, please visit www.radioligandtherapy.com/framework/us.

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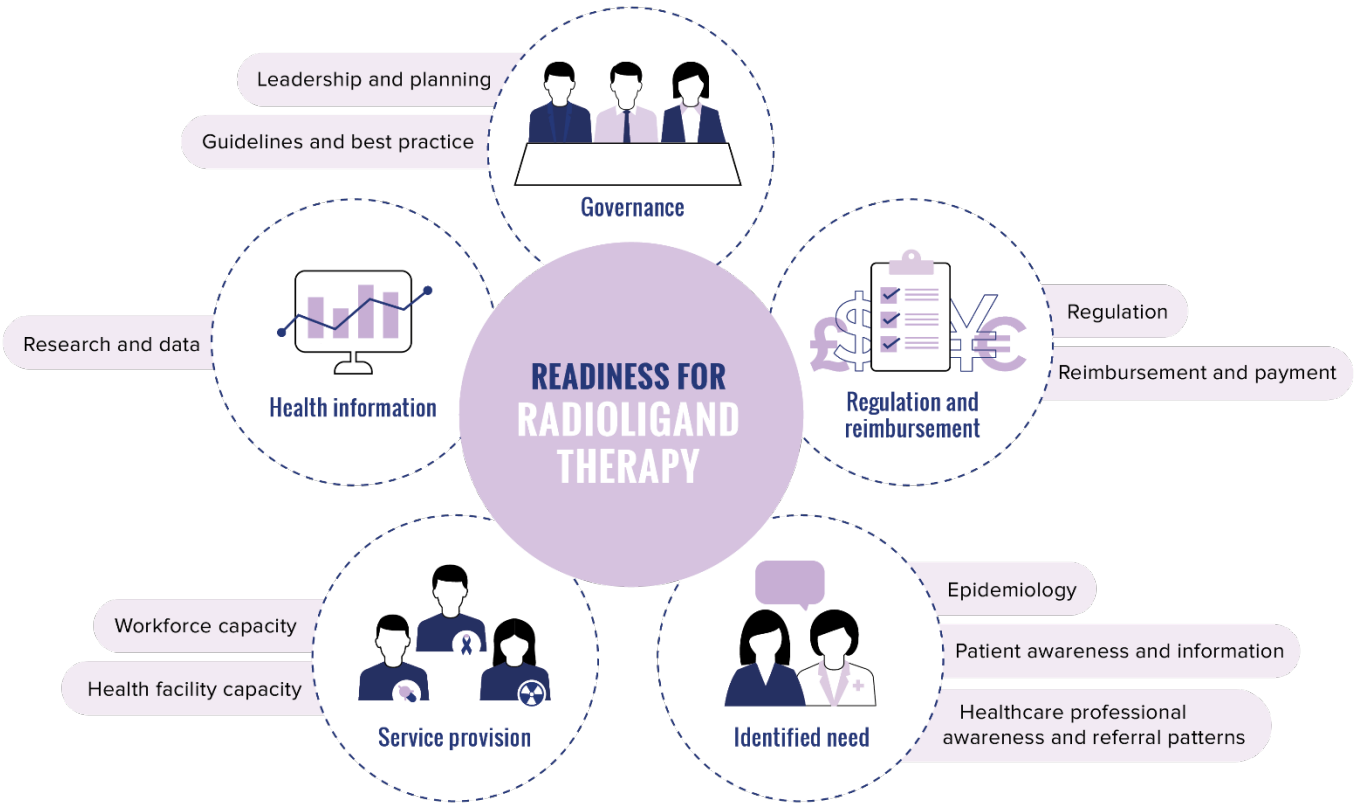
Introduction

The Radioligand Therapy Readiness Assessment Framework is an international tool that can help to establish the ability of health systems to rapidly and sustainably adapt policies, infrastructure and processes to support integration of a new radioligand therapy. The intention is that the framework can be adapted and applied to individual countries. This document is a national version of the framework following its application to the US.

Figure 1. A systems approach to readiness for radioligand therapy



For the full framework, and information on how it was developed and can be applied, please see www.radioligandtherapy.com/readiness-assessment-framework/

For an overarching summary of US findings, individual domain working papers and more information about the project, please see www.radioligandtherapy.com/framework/us

Terminology

This working paper uses the term radioligand therapy to refer to peptide receptor radionuclide therapy (PRRT), prostate-specific membrane antigen (PSMA) therapy, and radioimmunotherapy. We appreciate that there are a variety of other terms that may be used for radioligand therapy.

Radioligand therapy is a specific subtype of radiopharmaceutical therapies. Where possible, this working paper includes data relating to radioligand therapy. However, where research about radioligand therapy is not specifically available, we may refer more broadly to radiopharmaceutical therapies.

1 Governance

1.1 Leadership and planning

1.1.1 Are there any cancer strategies or plans in place in the US that include, or could include, radioligand therapy?

Metrics	• Which are the most relevant cancer strategies or plans and how are they organized? • How are cancer therapies considered? Is radioligand therapy included?
Contextual factors	• What is the reach and perceived influence of these strategies or plans? • Are there mechanisms in place to ensure these strategies or plans are implemented?

1.1.2 Are there any disease-specific strategies or plans in place in the US that include, or could include, radioligand therapy?

Metrics	*Assess separately for each indication where radioligand therapy has been authorized for use by the US Food and Drug Administration (FDA) or is in late-stage clinical trials.* • Is there a national disease management strategy or plan? • How are cancer therapies considered? Is radioligand therapy included?
Contextual factors	• How important are these strategies or plans in clinical practice? • Are there mechanisms in place at state level to ensure the strategy or plan is implemented?

1.1.3 Is there national leadership and political support for radioligand therapy?

Metrics	• Are patient organizations, professional societies and political groups actively involved in raising awareness and understanding of radioligand therapy? • Is radioligand therapy featured in policy discussions around cancer care?
Contextual factors	• Which stakeholders are involved in influencing policy change? • Are policymakers and decision-makers aware of radioligand therapy?

1.2 Guidelines and best practice

1.2.1 Do national disease-specific guidelines, published by any US professional society or health body, include radioligand therapy?

Metrics	*Assess separately for each indication where radioligand therapy has been authorized for use by the FDA or is in late-stage clinical trials.* • Do any disease-specific guidelines include radioligand therapy? In what circumstances is it recommended?
Contextual factors	• If more than one guideline exists for a specific disease, how do they differ? Who uses which guideline and under what circumstances?

1.2.2 Is there guidance for the delivery of radioligand therapy across clinical indications that is published centrally by any US professional society or health body?

Metrics	• Does guidance exist in the US for the delivery of radioligand therapy in general? • Does it provide guidance on: ◦ the roles and responsibilities of members involved in delivery? ◦ the built environment and equipment for delivery? ◦ preparation and administration of treatment? ◦ radiation protection and disposal of radioactive waste? • Are there local frameworks and/or protocols, published at hospital or state level, to support the implementation of national guidance for radioligand therapy in the local context?
Contextual factors	• If more than one piece of guidance exists, how do they differ? • Are these pieces of guidance actively used in the US health system? By which clinicians?

2 Regulation and reimbursement

2.1 Regulation

2.1.1 Are regulatory approval processes in the US suitable for radioligand therapy?

Metrics	• How is radioligand therapy classified by the FDA? • Has radioligand therapy been approved for use in the US? For which indications? • How does the FDA regulatory approval process work for diagnostics and associated radioligand therapies?
Contextual factors	• Is the FDA the only body responsible for providing regulatory approval for radioligand therapy? Do states make their own regulatory decisions?

2.1.2 Are regulations for the production and supply of radionuclides in the US appropriate for radioligand therapy?

Metrics	• How does the US obtain imaging and therapeutic radionuclides for radioligand therapy? • Are there mechanisms to ensure consistent supply of radionuclides into the US?
Contextual factors	• Are there any current or foreseen capacity issues in the supply of radionuclides for radioligand therapy? • Would the production, procurement or regulation of radionuclides need adaptation if use of radioligand therapy were to increase in the US?

2.1.3 Are regulations for the administration of radionuclides in the US appropriate for radioligand therapy?

Metrics	• What are the regulations for individuals working with medical radionuclides in the US? • What are the regulations for institutions providing radioligand therapy in the US?
Contextual factors	• How do regulatory issues in the licensing of medical professionals and employers/institutions impact access to radioligand therapy? • Is the current number of US healthcare professionals licensed to deliver radioligand therapy sufficient to meet potential increased demand?

2.1.4 Are regulations for the management of medical radioactive waste in the US applicable to radioligand therapy?

Metrics	• What are the regulations specific to the US for the management of radioactive waste? • Are differences in radionuclides considered, such as half-lives, purity and radiation quality?
Contextual factors	• Are US healthcare facilities able to manage current and future radioactive waste resulting from radioligand therapy?

2.2 Reimbursement and payment

2.2.1 How are existing US reimbursement and payment mechanisms applied to radioligand therapy?

Metrics	*Assess separately for each indication where radioligand therapy has been authorized for use by the FDA.* • Has radioligand therapy been granted reimbursement or undergone a health technology assessment that has led to its being covered by payers? ◦ If yes, by which body? ◦ If yes, what are the conditions for reimbursement/payment? • How is radioligand therapy funded (e.g. Medicare, Medicaid, commercial insurance)?
Contextual factors	• Are existing public- and private-payer clinical and economic evaluation evidence requirements considered applicable to, or appropriate for, radioligand therapy? • Would the level of reimbursement change if radioligand therapy were used in new and larger patient populations? • Is payment provided for imaging agents used to assess a person's eligibility for radioligand therapy?

3 Identified need

3.1 Epidemiology

3.1.1 What is the current burden of disease in the US?

Metrics	*Assess separately for each indication where radioligand therapy has been authorized for use by the FDA or is in late-stage clinical trials.* • What are the prevalence and incidence of conditions treated with radioligand therapy in the US?
Contextual factors	• How many people may be eligible for radioligand therapy in the US? • How are incidence and prevalence in the US expected to change in the next 5–10 years?

3.2 Patient awareness and information

3.2.1 Is there information for patients on radioligand therapy as a treatment option?

Metrics	*Assess separately for each indication where radioligand therapy has been authorized for use by the FDA or is in late-stage clinical trials.* • Is information available to US patients on radioligand therapy as a treatment option? • Does information on radioligand therapy clearly address eligibility criteria, delivery procedure, potential benefits, and side effects?
Contextual factors	• How and by whom is information disseminated?

3.3 Healthcare professional awareness and referral patterns

Please consider *Table A1* in the Appendix while answering the metrics in this section.

3.3.1 Are relevant healthcare professionals aware of radioligand therapy as a treatment option?

Metrics	*Assess separately for each indication where radioligand therapy has been authorized for use by the FDA or is in late-stage clinical trials.* • Do relevant healthcare professionals consider radioligand therapy when making treatment decisions?
Contextual factors	• How do previously available radioligand therapies impact healthcare professionals' perceptions of the therapy? • Is radioligand therapy covered as part of the training for the role? If so, how?

4 Service provision

4.1 Workforce capacity

Please consider *Table A2* in the Appendix while answering the metrics in this section.

4.1.1 How are Authorized Users involved in multidisciplinary therapeutic decision-making in the US?

Metrics	*Assess separately for each indication where radioligand therapy has been authorized for use by the FDA or is in late-stage clinical trials.* • What are the role and responsibilities of Authorized Users on cancer multidisciplinary tumor boards?
Contextual factors	• How will involvement of Authorized Users in tumor boards change if the use of radioligand therapy increases? • What are the key barriers and facilitators for collaboration between different categories of Authorized Users and tumor boards in the US?

4.1.2 Which healthcare professionals are involved in managing and delivering radioligand therapy in the US?

Metrics	*Assess separately for each indication where radioligand therapy has been authorized for use by the FDA or is in late-stage clinical trials.* • Which professionals are involved in managing and delivering radioligand therapy, and what are their roles and responsibilities in the care pathway? • At what point(s) in the pathway are they involved?
Contextual factors	• Who can prescribe radioligand therapy? • What barriers and facilitators exist in terms of ensuring optimal referral for and delivery of radioligand therapy? • Do referring healthcare professionals and the radioligand therapy team generally reside at the same institution e.g. same hospital or physician practice? How does this impact the provision of radioligand therapy?

4.1.3 Is there sufficient capacity in the US to meet current demand for radioligand therapy?

Metrics	*Assess separately for each healthcare professional included in the radioligand therapy team.* • How many healthcare professionals of each role are there in the US? • Is radioligand therapy included in the training curriculum for each role? • If yes, how is the therapy addressed?
Contextual factors	• Are there perceived gaps in training for radioligand therapy in the US? • Will the radioligand therapy team be able to keep pace with the potential increased demand for radioligand therapy in the US?

4.2 Health facility capacity

4.2.1 Are staging and eligibility assessments for radioligand therapy appropriate to meet current and future demand in the US?

Metrics	*Assess separately for each indication where radioligand therapy has been authorized for use by the FDA or is in late-stage clinical trials.* • What are the criteria for establishing eligibility for radioligand therapy and how are they established? • How many sites have imaging capacity for radioligand therapy across the US? • Is there an adequate number of trained professionals to perform imaging and interpret scans for radioligand therapy?
Contextual factors	• What barriers and facilitators exist to achieving optimal imaging capacity for radioligand therapy? • How will imaging capacity need to change if use of radioligand therapy increases?

4.2.2 How are radioligand therapy services organized in the US health system?

Metrics	*Assess separately for each indication where radioligand therapy has been authorized for use by the FDA or is in late-stage clinical trials.* • How many sites provide radioligand therapy in the US? • Are there criteria for becoming a site that delivers radioligand therapy? • Where does (or could) radioligand therapy sit in the indication's treatment pathway?
Contextual factors	• In which clinical or hospital department is radioligand therapy typically delivered? • How are radioligand therapy services distributed across the US? • What are the barriers and facilitators to the delivery of radioligand therapy at the clinical or hospital level?

4.2.3 Is the built environment in the US appropriate for the delivery of radioligand therapy?

Metrics	• Is radioligand therapy generally delivered as an inpatient or outpatient procedure? • Do sites delivering radioligand therapy have: ◦ a dedicated lead-lined room and bathroom for patients? ◦ appropriate storage space for radioactive waste?
Contextual factors	• Are there differences in the infrastructure for the delivery of radioligand therapy depending on the radionuclide that is used? • How will the built environment in the US need to be adapted if use of radioligand therapy increases?

5 Health information

5.1 Research and data

5.1.1 Is there sufficient data collection on radioligand therapy in the US to guide future planning and practice?

Metrics	• Are the following data collected in relation to radioligand therapy? ◦ Registry and audit data ◦ Real-world data on effectiveness in clinical practice ◦ Patient-reported outcomes data ◦ Economic data
Contextual factors	• To what extent are data used to support US healthcare workforce and system-level planning? • To what extent is it feasible to integrate data collection on the use of new treatments into existing data collection mechanisms such as the National Program of Cancer Registries (NPCR)? • What data are needed to support informed decision-making on radioligand therapy in the future?

Appendix

Table A1. Healthcare professionals involved in referrals for radioligand therapy in the US

Clinical indication	Relevant referring healthcare professionals
Neuroendocrine tumors	Endocrinologists, gastroenterologists, clinical/medical oncologists
Lymphoma	Hematologists, hemato-oncologists
Prostate cancer	Urologists, uro-oncologists, clinical/medical/radiation oncologists

Table A2. Care delivery teams in the US

Team	Healthcare professionals involved in each team
Radioligand therapy team	Nuclear medicine specialists, radiation oncologists, clinical/medical oncologists, clinical nurse specialists, radiopharmacists, medical physicists, patient coordinator
Tumor board	Clinical/medical/radiation oncologists, clinical nurse specialists, nuclear medicine specialists, radiologists, pathologists, surgeons, tumor board coordinator

About The Health Policy Partnership

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

About Avalere Health

Avalere Health is a vibrant community of innovative thinkers dedicated to solving the challenges of the healthcare system. Avalere delivers a comprehensive perspective, compelling substance, and creative solutions to help you make better business decisions. As an Inovalon company, Avalere prizes insights and strategies driven by robust data to achieve meaningful results.

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