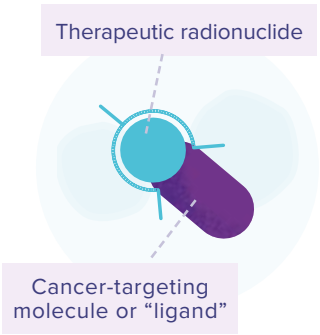
Creating a ready health system for radioligand therapy in the US

POLICY ACTION BLUEPRINT

What is radioligand therapy?

Radioligand therapy is a highly targeted cancer therapy. A radioligand is made of two parts: a ligand, which finds cancer cells that express a particular receptor or protein, and a radionuclide, which treats the cancer with radiation.[1,2] Radioligands find and deliver radiation directly to cancer cells, regardless of where these cells are located in the body. There are many terms for radioligand therapy, including peptide-receptor radionuclide therapy, molecular radiotherapy or, when the ligand used is an antibody, radioimmunotherapy.



Radioligand therapy has been shown to significantly improve survival and quality of life for people with certain types of neuroendocrine tumors (NETs), lymphoma, and prostate cancer.[3-10] More than conventional cancer therapies, radioligand therapy's targeted interaction with cancer cells leaves healthy cells largely unaffected.[1,11]

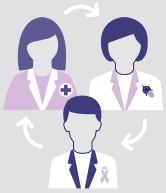
Readiness for radioligand therapy

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

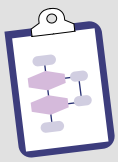
As new applications of radioligand therapy emerge and are supported by clinical data, we need to proactively plan for its integration into the US health system, to ensure it is made available to all people who may benefit from it.

6 KEY STRATEGIC CHALLENGES must be addressed to improve the current integration and future readiness for radioligand therapy in the US:

Awareness and training



Consensus building and multidisciplinary working



Referrals and care delivery

Financial feasibility

Equitable access

Data collection and analysis

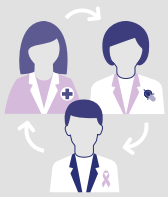
6 KEY STRATEGIC CHALLENGES

Awareness and training

Not all referring physicians have understanding or awareness of radioligand therapy, which can mean it is not considered for all appropriate patients

WE NEED:

- **All relevant medical professional organizations** to work with guideline committees and academic institutions to develop educational materials in order to: raise awareness among referring physicians; clarify their role along the radioligand therapy care pathway; and encourage them to consider the therapy in discussions with their patients
- **All relevant medical professional organizations and patient advocacy groups** to co-develop patient-facing materials about radioligand therapy to increase understanding of the therapy, delivery process, risks, and benefits

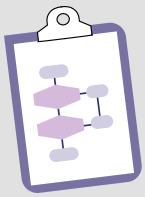


Consensus building and multidisciplinary working

Building consensus around the optimal timing and patient characteristics for radioligand therapy will help ensure that eligible patients are considered at the appropriate time

WE NEED:

- **All relevant guideline committees from the National Comprehensive Cancer Network, American Society of Clinical Oncology, and disease-specific professional bodies** to collaborate with nuclear medicine and radiation oncology professionals to ensure that adequate detail about approved radioligand therapy is promptly included in relevant guidelines
- **Professional medical societies and patient advocacy groups** to publish consensus statements that identify best practice for the coordination and delivery of radioligand therapy, and that can be replicated in most settings that offer the therapy



Referrals and care delivery

Clear referral pathways – adaptable to a range of care models, settings, and healthcare professionals – and delivery standards will ensure that radioligand therapy is seamlessly integrated into existing care pathways

WE NEED:

- **Hospitals, hospital networks, and academic health centers** to ensure all appropriate tumor board meetings have representation from nuclear medicine and/or radiation oncology specialists with knowledge of radioligand therapy
- **Professional medical societies or healthcare organizations** to work with industry to publish case studies of multidisciplinary referral pathways for all radioligand therapy indications that: include clear descriptions of eligible patient populations and sequencing; and are adaptable to care in community and specialist cancer centers

Financial feasibility

If practices do not see radioligand therapy as a sustainable investment, they are unlikely to make it available to their providers and patients. Whether a center delivers radioligand therapy or refers patients, the costs need to be appropriately covered by health insurance

WE NEED:

- **Industry, patient advocacy groups, and institutions currently providing radioligand therapy** to clarify the business case for centers to expand or set up a radioligand therapy referral or delivery service and advise on how to optimize the reimbursement process
- **Insurers and payers** to develop reimbursement policies and guidance documents for providers and hospital administrators that are aligned with consensus-driven quality standards and clinical guidelines

Equitable access

Radioligand therapy is typically provided in a small number of well-resourced centers, which limits its availability for people who are eligible but unable to reach those centers

WE NEED:

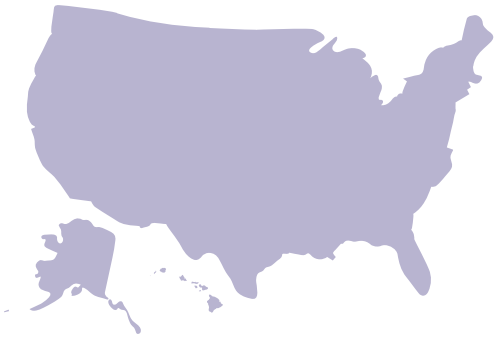
- **Industry, insurers, and care providers** to support initiatives to improve equitable availability of therapies and expertise, including through the use of telemedicine and social service initiatives
- **Healthcare professionals and insurers** to continue to integrate innovative models of care, such as remote multidisciplinary team meetings and consultations, to improve equitable access to expertise in radioligand therapy

Data collection and analysis

Data collection for radioligand therapy is currently limited or fragmented, making it difficult to build consensus on the clinical need for the therapy, as well as the appropriate sequencing and provision of treatments. Limited data collection also impedes planning for future infrastructure demands

WE NEED:

- **Professional medical societies, patient advocacy groups, research institutes, and registry and database owners or managers** to develop a consensus-driven, standard data set on radioligand therapy that can be integrated into existing data collection practices
- **Industry and healthcare professionals** to support increased data collection for radioligand therapy. The data set should include:
  - use of radioligand therapy or other radiopharmaceutical therapies; related quality-of-life and other patient-reported outcomes; and long-term clinical outcomes
  - data on radioligand therapy workforce and delivery infrastructure in each locality
- **Professional medical societies and patient advocacy groups** to submit requests for the Surveillance, Epidemiology, and End Results (SEER) Program to track use of radioligand therapy and other radiopharmaceutical therapies in patient care



Why does the US need to be ready for the wider use of radioligand therapy?

Radioligand therapy is currently licensed in NETs and lymphoma, and the US Food and Drug Administration (FDA) has clearly recognized its value to people with cancer. The FDA reviewed radioligand therapy for NETs and lymphoma through the prioritized pathway[12 13] and, in June 2021, granted a breakthrough therapy status for radioligand therapy in metastatic castration-resistant prostate cancer (mCRPC).[14]

Given the growing number of people who may be eligible for radioligand therapy, it is important to understand which policies, processes, and models of care must be modified to ensure its availability to all who need it. Radioligand therapy could, theoretically, be applied to any cancer where a suitable receptor is identified. It is currently under investigation for prostate, breast, and other types of cancer;[15-19] this could mean a significant increase in patient numbers. As the number of people who might benefit from radioligand therapy grows – and models of care shift from large academic centers to community-based practices – we need to rethink our infrastructure, workforce, reimbursement systems, and models of care to ensure equitable and timely access.

A proactive approach to planning is essential for equitable integration of radioligand therapy into patient care. The decentralized and complex health policy environment is an ongoing challenge. But with concerted collaboration, communication, and consensus building across the radioligand therapy community, we can ensure that people who might benefit from the therapy are able to receive the care they need.

REFERENCES

1. Jadvar H. 2017. *AJR Am J Roentgenol* 209(2): 277-88
2. Fahey F, *et al.* 2014. *J Nucl Med* 55(2): 337-48
3. Strosberg J, *et al.* 2017. *N Engl J Med* 376(2): 125-35
4. Marinova M, *et al.* 2018. *Eur J Nucl Med Mol Imaging* 45(1): 38-46
5. Cheson BD. 2003. *Blood* 101(2): 391-98
6. Kolstad A, *et al.* 2018. *Blood*: 10.1182/blood-2018-99-110555
7. Witzig TE, *et al.* 2002. *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, *et al.* 2021. *N Engl J Med*: 10.1056/NEJMoa2107322
11. Herrmann K, *et al.* 2020. *Lancet Oncol* 21(3): e146-e56
12. Biospace. https://www.biospace.com/article/fda-accepts-cell-therapeutics-inc-s-zevalin-sbla-and-grants-priority-review-may-accelerate-first-line-launch-by-four-months-/
13. U.S Food and Drug Administration. https://www.fda.gov/news-events/press-announcements/fda-approves-new-treatment-certain-digestive-tract-cancers
14. Reuters. 2021. https://www.reuters.com/business/healthcare-pharmaceuticals/novartis-prostate-cancer-drug-receives-us-fda-breakthrough-designation-2021-06-16/
15. ClinicalTrials.gov. https://www.clinicaltrials.gov/ct2/show/NCT04529044
16. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT00445965
17. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT03971461
18. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT04022213
19. ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT03392428

The Health Policy Partnership

ABOUT THE RADIOLIGAND THERAPY READINESS ASSESSMENT PROJECT

This policy action blueprint 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 materials, including a US situation analysis report, working papers on health system readiness for radioligand therapy in the US, and an associated national framework.

All documents have been developed by The Health Policy Partnership with support from Avalere Health and in collaboration with a US Expert Advisory Group. The project is supported through an unrestricted grant from Advanced Accelerator Applications, a Novartis Company, with additional support from Nordic Nanovector. For more details, please visit **www.radioligandtherapy.com/framework/US**