PROGRAM OVERVIEW: RAGIOLIGAND THERAPY

WHAT is RLT - and Why It Matters

A targeted cancer treatment delivering localized radiation directly to tumor cells — combining oncology, nuclear medicine, imaging, pharmacy, radiation safety, and payer strategy into one integrated program.

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HOW IT WORKS

1. A biologic ligand targets a tumor-specific receptor on cancer cells.
2. A therapeutic radioisotope is attached to the ligand.
3. Radiation is delivered directly to the tumor, sparing surrounding tissue.
4. Imaging (theranostics) confirms target expression before therapy begins.

THE THERANOSTIC MODEL

Diagnose + Treat with the Same Ligand

The diagnostic scan confirms the tumor target is expressed. Therapy uses the same (or similar) ligand with a therapeutic isotope attached.

COMPLEXITY BY THERAPY

Pluvicto®	Medium
Lutathera®	High
Xofigo®	Low-Medium

WHY COMMUNITY PROGRAMS WIN

- Faster scheduling than hospital systems
- More physician-friendly access model
- Shorter prior authorization timelines
- Patients remain in your care after treatment

PROGRAM COMPONENTS

- Oncology
- Nuclear medicine
- Diagnostic imaging
- Pharmacy & logistics
- Radiation Safety
- Payer & authorization strategy

FDA APPROVED THERAPIES

Pluvicto® (Lu-177 vipivotide tetraxetan)

Metastatic castration-resistant prostate cancer (mCRPC)

Lu-177 (beta emitter) | Every 6 weeks | Up to 6 cycles | PSMA PET required

Best for practices with strong urology relationships and PSMA imaging access. Patients travel further for this therapy given urgency and limited site availability.

Lutathera® (Lu-177 DOTATATE)

Somatostatin receptor–positive neuroendocrine tumors (NETs)

Lu-177 (beta emitter) | Every 8 weeks | 4 cycles | 5-8 hr visit | Amino acid infusions required

Best for practices willing to run a high-discipline, protocol-heavy program. Winning 2–3 NET specialists can give you regional market ownership.

Xofigo® (Radium-223 dichloride)

Metastatic CRPC with bone-predominant metastases

Ra-223 alpha emitter | Monthly | 6 doses | No imaging required | Low infastructure burden

Best entry point for practices new to RLT. Simpler administration, no imaging prerequisite, and lower compliance overhead than Lu-177 agents.

Leadership Directive: RLT is not "just another drug." It is a full program combining oncology, nuclear medicine, imaging, pharmacy, radiation safety, payer strategy, and logistics — all working in concert.

STEP 1: MARKET ANALYSIS

How to Evaluate Your RLT Market

Determine whether your organization can capture patients, convert referrals, get reimbursed, deliver therapy consistently, and reach break-even volume before committing to launch.

DEFINE YOUR CATCHMENT AREA

0 - 30 miles

Primary Zone:

Easiest patient capture from practices within direct travel range. Highest expected conversion rate. Target all oncology, urology, and NET specialists here first.

30 - 60 miles

Secondary Zone:

Strong opportunity when scheduling access is frictionless. Patient navigation support significantly increases capture. Outcompete on turnaround speed and referral communication.

60 - 100 miles

Extended Zone:

Extended Zone — 60–100 miles Viable only if you outperform hospital systems on every friction point. Requires travel-friendly navigation, fast auth, and clear referral pathways. Pluvicto and Lutathera patients travel further; Xofigo less so.

CATCHMENT IS FRICTION BASED, NOT DISTANCE BASED

Adjust based on: Population Density

- **Dense metro** = smaller viable radius — patients have many local options
- **Rural/suburban** = larger radius — patients already travel for specialty care
- Referral Travel Tolerance (Reality Check)

In General

- Pluvicto patients travel more (higher urgency, fewer sites)
- Lutathera patients travel if the program is “NET-friendly”
- Xofigo patients travel less (more commoditized, older therapy)

REFERRAL SOURCE MAPPING BY THERAPY

PRIMARY DRIVERS: Pluvicto®

- High-volume urology groups (esp. those hiring med oncs)
- Medical oncology groups treating mCRPC patients
- Large prostate cancer clinics
- Hospital systems that lack internal RLT capability

High signal: urology groups integrating oncology service

PRIMARY DRIVERS: Lutathera®

- NET specialists
- GI oncology
- endocrinology networks
- academic NET clinics that are overloaded

NET is referral-driven and relationship-driven. If you win 2–3 NET specialists, you can own the market.

PRIMARY DRIVERS: Xofigo®

- older med onc groups
- community urology groups
- practices with bone metastasis volume

But note: Xofigo has been partially displaced by Pluvicto.

REFERRAL LEAKAGE - CRITICAL QUESTIONS

- "Where are your patients currently going for RLT treatment?"
- "Why there — and do you get them back after treatment?"
- "How long does it take to get your patients scheduled there?"
- "Does that program make your team handle prior authorization?"
- "Do they keep the patient long-term after completing therapy?

COMPETITOR ANALYSIS FRAMEWORK

Create a table that includes:

- Facility name
- type (academic/hospital/community/private)
- distance from site
- RLT therapies offered
- Frequency (weekly? monthly?)
- Known backlog (if any)
- Referral reputation (good vs painful)
- Contact name (nuclear med lead or admin)

Key Directive: A referral relationship is not sending patients. It's sending patients and getting them back. If you cannot guarantee co-management and communication, your referral pipeline will leak.

STEP 2: PAYER STRATEGY

PAYER MIX & COVERAGE REALITY

This is where most RLT business plans break. Payer mix quality often matters more than raw patient volume — understand your local landscape before you commit to launch.

PAYER MIX FRAMEWORK

Medicare Traditional

- Anchor payer for most RLT programs.
- Typically smoother and faster operationally than commercial.
- Lower reimbursement, but more predictable and less friction.

Medicare Advantage

- Behaves like commercial — slow, denial-prone.
- Apply the same scrutiny and documentation prep as for commercial.
- Plan-specific coverage criteria vary significantly by carrier.

Commercial Insurance

- Higher reimbursement potential but significantly longer delays.
- Denies more frequently and requires more documentation.
- Peer-to-peer review is common — build a physician champion

Medicaid / Self-Pay

- Usually minimal volume for RLT patient population.
- Factor into access and equity planning only.
- Do not build revenue projections around this payer segment

AUTHORIZATION COMPLEXITY

- RLT is high-dollar, high-scrutiny authorization — not standard infusion auth.
- Pluvicto: prior treatment confirmation required at prior auth.
- Lutathera: SSTR imaging documentation required.
- Step therapy requirements are common among commercial plans.
- Assume delays are normal. Approval is never guaranteed.
- Speed of authorization is a direct competitive differentiator.

COMMERCIAL VS MEDICARE: OPERATIONAL REALITY

MEDICARE TRADITIONAL

Faster approval, smoother ops, lower reimbursement

MEDICARE ADVANTAGE

Commercial-like behavior — plan-specific criteria apply

COMMERCIAL INSURANCE

Higher dollar, more denials, longer lag to payment

AUTHORIZATION COMPLEXITY

- Which plans dominate your catchment area?
- Which plans are known to deny nuclear medicine therapies?
- Which payers require peer-to-peer review before approval?
- Which payers route cases to "center of excellence" sites only?
- Historical denial rates and auth timelines at competing sites
- Reimbursement trends over the past 12–18 months
- Payer mix shift patterns (commercial to Medicare Advantage)

PRIOR AUTHORIZATION: KEY FRICTION POINTS

IMAGING PREREQUISITES

- PSMA PET scan required for Pluvicto — must be completed and fully documented.
- SSTR imaging required for Lutathera prior authorization.

STEP THERAPY REQUIREMENTS

- Prior lines of therapy must be documented and confirmed as failed.
- Different payers define step therapy criteria differently — know each plan.

DOCUMENTATION & PEER-TO-PEER

- Missing pathology, lab values, or treatment records are the top denial drivers.
- Build a physician champion who can handle P2P reviews efficiently and quickly.

Reality Check: A market with 15 patients/month but poor coverage can lose money. A market with 8–10/month and stable Medicare can succeed. Volume without reimbursement reliability is not a viable business.

STEP 3: MANUFACTURER CONTRACTING

Securing Your Product Supply & Contract

If you cannot secure a clean manufacturer pathway for ordering, delivery, returns/waste, and billing support — your RLT program is not operational, regardless of licensing status.

DISTRIBUTION MODELS BY MANUFACTURER

Pluvicto - Novartis

- Tightly controlled distribution — historically capacity-constrained.
- Manufacturing slot allocation required well in advance of treatment.
- Direct access; your leverage depends on volume commitment made

Lutathera - Novartis

- Controlled scheduling with pre-planned manufacturing slots.
- Quarterly slot allocation — plan your patient schedule far in advance.
- Protocol complexity requires close coordination with manufacturer reps.

Xofigo - Bayer

- More mature and flexible distribution model than Lu-177 agents.
- Lower allocation friction — easier to access and schedule reliably.
- Best entry point operationally for new RLT programs.

READINESS CHECKLIST BEFORE YOU NEGOTIATE

- [ ] NRC or Agreement State licensing documentation ready
- [ ] Authorized User (AU) and RSO credentials confirmed on staff
- [ ] Radiation safety policies and waste handling SOPs complete
- [ ] Shielding documentation and site inspection readiness confirmed
- [ ] Dedicated ordering contact and scheduling staff identified
- [ ] Ordering portal training completed by relevant staff
- [ ] Onboarding timeline (60–120 days) integrated into launch plan

PRICING & CONTRACT STRUCTURE

- WAC vs ASP-based methodology vs GPO contract pricing?
- Is there a community oncology pricing tier available?
- Can pricing improve with volume commitments or ramp schedule?
- Penalties for missing volume projections — how are they structured?
- Annual price escalators — what is the mechanism and cap?

PAYMENT TERMS - THIS CAN MAKE OR BREAK YOU

Working Capital Risk

If payer reimbursement lag is 60–120 days and manufacturer terms are Net 30, you may need millions in working capital before your first patient is treated. Negotiate extended terms or consignment arrangements for new sites before signing any agreement.

PAYMENT TERMS - QUESTIONS TO ASK

- Standard terms offered: Net 30, Net 45, or Net 60?
- Extended terms available for new program sites?
- Credit review process and typical limits for new accounts?
- Consignment or delayed billing until dose is administered?
- What happens operationally if your first 3 claims are denied?

ORDERING, DELIVERY & WASTE POLICY

ORDERING & SCHEDULING CONTROL

- How far in advance must doses be ordered?
- Can slots be reserved before authorization is complete?
- Correct sequence: authorization → schedule → order
- Who controls final ship approval — you or manufacturer

DELIVERY & CHAIN-OF-CUSTODY

- What carrier is used and what is the delivery window?
- Who signs custody and what documentation is required?
- Protocol for damaged, delayed, or mis-delivered shipments
- Chain-of-custody errors are reportable events — confirm workflow

CANCELLATION, RETURNS & WASTE

- Cancellation window without financial penalty? If patient is hospitalized or dies — are you still billed
- Partial credit or replacement for unused doses?
- Waste documentation policy and proof-of-disposal requirements

STEP 4: CONTRACTING RED FLAGS & LAUNCH READINESS

What to Watch For — and How to Know You're Ready

Before signing contracts or committing to a launch date, validate your program against these red flags and readiness criteria. Every item on the right should be checked before treating your first patient.

MANUFACTURER CONTRACTING RED FLAGS

Red Flag #1

Vague onboarding promises.

'We can onboard you quickly' without a documented timeline means chaos. Demand a written onboarding checklist with milestone dates before any agreement is signed.

Red Flag #2

Short cancellation window + strict billing.

If you cannot cancel a dose within a reasonable window without penalty, your waste risk is financially dangerous. One hospitalized patient equals one wasted high-cost do

Red Flag #3

No real reimbursement support.

Weak manufacturer support teams offer generic PDFs instead of payer-specific auth templates, denial appeal packs, and accurate coding guidance. Ask for examples before you rely on their support.

Red Flag #4

Payment terms misaligned with payer lag.

Net 30 manufacturer terms against 90–120 day payer reimbursement = cash flow crisis before you establish volume. This is how RLT programs run out of money in year one

Red Flag #5

No clarity on slot allocation.

If they cannot explain exactly how manufacturing slots are reserved and released, you cannot build a reliable patient schedule. This is a program-breaking operational risk

PROGRAM LAUNCH READINESS CHECKLIST

Licensing & Compliance

- NRC or Agreement State license obtained and active
- Authorized User (AU) credentialed and on staff
- RSO (Radiation Safety Officer) formally designated
- Radiation safety plan and waste handling SOPs finalize

Facility & Infrastructure

- Radiation shielding verified and fully documented
- Hot lab or designated dose preparation space is ready
- Treatment room meets all radiation containment standards
- Dosimetry equipment calibrated, validated, and approved

Clinical & Operational

- Clinical protocol developed for each therapy being offered
- Nursing staff trained on administration and radiation safety
- Imaging access confirmed (PSMA PET, SSTR imaging as needed)
- Amino acid infusion protocol in place for Lutathera patients

Contracting & Payer

- Manufacturer contract executed (pricing, terms, waste policy)
- GPO affiliation reviewed and leveraged for pricing advantage
- Payer coverage analysis complete for top local plans
- Prior authorization workflow built, documented, and staff-tested

Referral & Go-to-Market

- Referral source map completed by therapy type
- At least 2–3 anchor referrers confirmed per therapy offered
- Patient navigation and scheduling workflow defined and tested
- Co-management communication protocol in place with referrers