Anthem

Clinical UM Guideline

Subject: Inpatient Admission for Radiation Therapy for Cervical or Thyroid Cancer
Guideline #: CG-MED-38
Status: Reviewed
Publish Date: 01/03/2024
Last Review Date: 11/09/2023

Description

This document addresses the medical necessity of an inpatient admission for radiation treatment for cervical and thyroid cancer. Radiation implants, also called brachytherapy, may be placed in interstitial or intracavitary spaces for the treatment of cervical cancer. Thyroid cancer may be treated with radioactive iodine such as I-131. Individuals are discharged from the hospital after the radiation implants are removed and the levels of radioactivity are deemed safe and appropriate for discharge.

Note:

- This document does not address the use of I-131, a radioactive substance when used as a diagnostic tool in an I-131 scan.
- Federal or State regulations will supersede the guideline Length of Stay included under both Clinical Indications section and Goal Length of Stay (GLOS) sections.

Clinical Indications

Medically Necessary:

An inpatient admission for radiation treatment for cervical or thyroid cancer is considered**medically necessary** for the period of time the individual's calculated level of radioactivity is greater than the discharge guidelines set by the U.S. Nuclear Regulatory Commission (USNRC, 2020). See Appendix A.

Not Medically Necessary:

An inpatient admission for radiation treatment for cervical cancer or thyroid cancer is considered**not medically necessary** when the above criteria are not met.

Goal Length of Stay

Goal Length of Stay:	Generally 1-2 days. The Radiation Safety Department will clear the individual for discharge when the individual emits a safe level of radiation.

Coding

Coding edits for medical necessity review are not implemented for this guideline. Where a more specific policy or guideline exists, that document will take precedence and may include specific coding edits and/or instructions. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Discussion/General Information

Brachytherapy, or cervical radiation implants, is a component of therapy for those with primary cervical cancer who are not surgical candidates. High-dose rate (HDR) brachytherapy, which involves exposing the target area to strong radiation for short periods of time, is done on an outpatient basis. The implant remains only an hour or less and is done weekly repeated three to five times. Low-dose rate (LDR) brachytherapy requires that the radiation source be left in place from approximately 1 to 4 days. LDR brachytherapy is applied using an intracavitary, interstitial or a combination approach (Banerjee, 2014). Interstitial implants containing the radioactive material are placed next to the target area using either an applicator or catheters. The individual may remain hospitalized until the implants are removed and the individual meets discharge criteria.

Generally, for thyroid cancer, I-131 therapy is done after a total or a partial thyroidectomy. The thyroid absorbs almost all of the body's iodine. I-131 is used to destroy cancer cells that take up iodine and were not removed by surgery and those that have spread beyond the thyroid (American Cancer Society [ACS], 2019). Therapy is given in either liquid or pill form. Dosing of the therapy can be calculated using an empiric or fixed dosing, quantitative dosimetry, or upper bound limits set by blood dosimetry (National Comprehensive Cancer Network® [NCCN®], 2023). The most widely used and the simplest method is the empiric or fixed dose. The individual's dose is determined by the extent of their disease with typical doses within 30-200 mCi (NCCN, 2022). In the past, individuals were routinely hospitalized for I-131 radiation therapy. Hospitalization is no longer routinely required because a change in federal legislation permits the use of much larger doses in ambulatory individuals (NCCN, 2023; U.S. Nuclear Regulatory Commission [USNRC], 2019). Wu and associates (2020) surveyed thyroid cancer survivors to evaluate practice changes regarding hospital release of individuals with differentiated thyroid cancer treated with I-131. Prior to 2009, approximately 66% of thyroid cancer survivors were treated in the outpatient setting. After 2011, the rate of thyroid cancer survivors treated in the outpatient setting has risen to 87%.

Individuals are encouraged to drink fluids to help the I-131 pass quickly through the body. I-131 is excreted in all body fluids. Therefore, all objects coming into contact with the individual that may be contaminated with sweat, urine, feces, blood or other body fluids are considered radioactive. Within a few days, most of the radiation has been excreted.

According to the U.S. Nuclear Regulatory Commission regulations (2020), individuals treated with various forms of radioactive implants may be released from the treating facility's control when contact with that individual will not expose others to a total effective dose equivalent not likely to exceed 5 millisieverts (mSv) (0.5 rem). The facility must also provide the affected individual or caregiver with written instructions to minimize exposure to others to as low as is reasonably achievable (ALARA). A radiation survey is done prior to discharge. There are 3 pathways to determine the dose rate at which individuals can be released. These are based upon the

level and type of radionuclide administered during therapy. Local or State regulations may differ from the U.S. Nuclear Regulatory Commission (USNRC, 2020). For safety, the survey requires exposure rate radiation levels be determined in the individual's room and the surrounding area, recorded, and maintained for inspection by the department.

References

Peer Reviewed Publications:

1. Al-Shakhrah IA. Radioprotection using iodine-131 for thyroid cancer and hyperthyroidism: a review. Clin J Oncol Nurs. 2008; 12(6):905-912.
2. Banerjee R, Kamrava M. Brachytherapy in the treatment of cervical cancer: a review. Int J Womens Health. 2014; 6:555-564.
3. Brooks SE, Chen TT, Ghosh A, et al. Cervical cancer outcomes analysis: impact of age, race, and comorbid illness on hospitalizations for invasive carcinoma of the cervix. Gynecol Oncol. 2000; 79(1):107-115.
4. de Carvalho J, Sapienza M, Ono C, et al. Could the treatment of differentiated thyroid carcinoma with 3.7 and 5.55 GBq of (131I)NaI, on an outpatient basis, be safe? Nucl Med Commun. 2009; 30(7):533-541.
5. Willegaignon J, Sapienza M, Ono C, et al. Outpatient radioiodine therapy for thyroid cancer: a safe nuclear medicine procedure. Clin Nucl Med. 2011; 36(6):440-445.
6. Wu D, Gomes Lima CJ, Bloom G, et al. Nationwide survey on implementation of 2011 Nuclear Regulatory Commission policy on release of patients after 131I therapy for thyroid cancer. J Nucl Med. 2020; 61(3):397-404.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American College of Radiology (ACR), the American College of Nuclear Medicine (ACNM), the American Society for Radiation Oncology (ASTRO), the Society of Nuclear Medicine and Molecular Imaging (SNMMI), and the Society for Pediatric Radiology (SPR) Practice Parameter for Treatment of Benign and Malignant Thyroid Disease with I131 Sodium Iodide. Adopted 2019. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/I131SodiumIodide.pdf. Accessed on September 29, 2023.
2. ACR–ACNM–ASTRO–SNMMI Practice Parameter for the Performance of Therapy with Unsealed Radiopharmaceutical Sources. Revised 2023. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/UnsealedSources.pdf. Accessed on September 29, 2023.
3. American Thyroid Association Taskforce on Radioiodine Safety. Radiation safety in the treatment of patients with thyroid diseases by radioiodine 131I: practice recommendations of the American Thyroid Association. Thyroid. 2011; 21(4):335-346.
4. Henkin RE, Del Rowe JD, Grigsby PW, et al. ACR-ASTRO practice guideline for the performance of therapy with unsealed radiopharmaceutical sources. Clin Nucl Med. 2011; 36(8):e72-e80.
5. Luster M, Clarke SE, Dietlein M, et al.; European Association of Nuclear Medicine (EANM). Guidelines for radioiodine therapy of differentiated thyroid cancer. Eur J Nucl Med Mol Imaging. 2008; 35(10):1941-1959.
6. National Cancer Institute (NCI). Available at: http://www.cancer.gov/publications/pdq. Accessed on September 29, 2023.
    - Cervical Cancer Treatment. Modified June 2, 2023.
    - Thyroid Cancer Treatment. Modified July 21, 2023.
7. National Comprehensive Cancer Network® (NCCN). Clinical Practice Guidelines in Oncology®. ©2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on September 29, 2023.
    - Cervical Cancer. V.1.2024. September 20, 2023.
    - Thyroid Carcinoma. V.4.2023. August 16, 2023.
8. Spratt D, Zaki BI, Franc BL, et al. ACR practice parameter for the performance of therapy with unsealed radiopharmaceutical sources. Clin Nucl Med. 2016; 41(2):106-117.
9. U.S. Nuclear Regulatory Commission (USNRC).
    - § 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material. Page updated August 29, 2017. Available at: http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0075.html. Accessed on September 29, 2023.
    - Consolidated guidance about materials licenses. Program-specific guidance about medical use licenses. Final report. NUREG-1556, Vol. 9, Rev 3. Page updated September 2019. Available at: https://www.nrc.gov/docs/ML1925/ML19256C219.pdf . Accessed on September 29, 2023.
    - NRC policy on release of iodine-131 therapy patients under 10 CFR 35.75 to locations other than private residences. RIS 2011-01. January 25, 2011. Available at: http://pbadupws.nrc.gov/docs/ML1036/ML103620153.pdf. Accessed on September 29, 2023.
    - Regulatory Guide 8.39 Revision 1. Release of Patients Administered Radioactive Material. April 2020. Available at: https://www.nrc.gov/docs/ML1923/ML19232A081.pdf. Accessed on September 29, 2023.

Websites for Additional Information

1. American Cancer Society. Accessed on September 24, 2023.
    - Getting Internal Radiation Therapy (Brachytherapy). Available at: https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/radiation/internal-radiation-therapy-brachytherapy.html. Last Revised December 27, 2019.
    - Radioactive Iodine (Radioiodine) Therapy for Thyroid Cancer. Available at: https://www.cancer.org/cancer/thyroid-cancer/treating/radioactive-iodine.html. Last Revised February 28, 2023.
2. American Thyroid Association. Radioactive Iodine. Available at: https://www.thyroid.org/radioactive-iodine/. Accessed on September 24, 2023.
3. National Cancer Institute (NCI). Radiation Therapy to Treat Cancer. Updated January 8, 2019. Available at: https://www.cancer.gov/about-cancer/treatment/types/radiation-therapy#TCRT. Accessed on September 24, 2023.

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History

Status	Date	Action
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Description, Discussion and References sections.
Reviewed	11/10/2022	MPTAC review. Updated Discussion and References sections.
Reviewed	11/11/2021	MPTAC review. Updated Discussion, References and Websites sections.
Revised	11/05/2020	MPTAC review. Revised year of the U.S. Nuclear Regulatory Commission referenced in the clinical indications. Updated Discussion, References and Appendix sections.
Reviewed	11/07/2019	MPTAC review. Updated Description, Discussion, References and Websites sections.
Revised	01/24/2019	MPTAC review. Revised citation year of the U.S. Nuclear Regulatory Commission (USNRC) from 20013 to 2013. Updated Discussion, References and Websites sections.
	09/20/2018	Updated Coding section; removed procedure and diagnosis codes as specific coding is not applicable.
Reviewed	02/27/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Discussion, References and Websites sections.
Reviewed	02/02/2017	MPTAC review. Updated Description, Discussion, References and Websites sections.
Reviewed	02/04/2016	MPTAC review. Updated Description, Discussion, References and Websites sections.
	01/01/2016	Updated Coding section with 01/01/2016 CPT changes, removed 77776, 77777 deleted 12/31/2015; also removed ICD-9 codes.
Reviewed	02/05/2015	MPTAC review. Updated Description, Coding, References and Websites sections.
Reviewed	02/13/2014	MPTAC review. Updated References and Websites sections.
Reviewed	02/14/2013	MPTAC review. Updated References and Websites sections.
Reviewed	02/16/2012	MPTAC review. Updated References and Websites sections.
	01/01/2012	Updated Coding section with 01/01/2012 CPT descriptor revisions.
Reviewed	02/17/2011	MPTAC review. Updated References and Websites sections. Updated Coding section with 04/01/2011 HCPCS changes; removed S2270 deleted 03/31/2011.
	10/14/2010	Category changed from CG-RAD-19 to CG-MED-38. Updated Website information.
Reviewed	02/25/2010	MPTAC review. References and websites updated.
Revised	02/26/2009	MPTAC review. References, websites and coding updated. Clinical indications clarified and Appendix A added. Place of Service Section removed.
Reviewed	02/21/2008	MPTAC review. References, websites updated. No change to position.
	01/01/2008	Updated Coding section with 01/01/2008 CPT changes.
New	03/08/2007	MPTAC review. Initial guideline development. Combined CG-RAD-03 Inpatient Admission for I-131 Radiation Treatment for Thyroid Cancer with CG-RAD-17 Radiation Implants for Cervical Cancer Length of Stay. Description, discussion, references and coding updated.

Appendix A (Return to Clinical Indications)

U.S. Nuclear Regulatory Commission (USNRC). Release of Patients Administered Radioactive Material. Regulatory Guide 8.39 Revision 1. Issue Date: April 2020. Available at: https://www.nrc.gov/docs/ML1923/ML19232A081.pdf. Accessed on November 2, 2023.

1.1 Release of Patients Based on the Administered Activity: One means that licensees may use to comply with the dose limit in 10 CFR 35.75(a) is to release patients from licensee control if the dosage administered is not greater than the activity in Column 1 of Table 1.**1.2 Release of Patients Based on the Measured Dose Rate:**Licensees may release patients to whom radionuclides have been administered in amounts greater than the activities listed in Column 1 of Table 1 as long as the measured dose rate at 1 meter (from the surface of the patient) is no greater than the value in Column 2 of Table 1 for that radionuclide.

1.3 Release of Patients Based on Patient-Specific Dose Calculations: Licensees may release patients based on dose calculations using patient-specific parameters. With this method, in accordance with 10 CFR 35.75(a), the licensee must calculate the maximum likely dose to an individual exposed to the patient on a case-by-case basis. If the calculated maximum likely dose to an individual is no greater than 5 mSv (0.5 rem), the licensee may release the patient. Using this method, licensees may be able to release patients with activities greater than those listed in Column 1 of Table 1 by accounting for the effective half-life of the radioactive material and other factors that may be relevant to the particular case. If the dose calculation considered retained activity, an occupancy factor less than 0.25 at 1 meter, the effective half-life, or shielding by tissue, then 10 CFR 35.2075(a) requires the licensee to maintain a record of the basis for authorizing the patient’s release.

Table 1 Activities and Dose Rates for Authorizing Patient Release[a]

Radionuclide	Column 1 Activity at or Below Which Patients May be Released		Column 2 Dose Rate at 1 Meter, at or Below Which Patients May be Released[b]	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
Ag-111	19	520	0.08	8
Au-198	3.5	93	0.21	21
Cr-51	4.8	130	0.02	2
Cu-64	8.4	230	0.27	27
Cu-67	14	390	0.22	22
Ga-67	8.7	240	0.18	18
I-123	6	160	0.26	26
I-125	0.25	7	0.01	1
I-125 implant	0.33	9	0.01	1

Radionuclide	Column 1 Activity at or Below Which Patients May be Released		Column 2 Dose Rate at 1 Meter, at or Below Which Patients May be Released[b]	
	(GBq)	(mCi)	(mSv/hr)	(mrem/hr)
I-131	1.2	33	0.07	7
In-111	2.4	64	0.2	20
Ir-192 implant	0.074	2	0.008	0.8
P-32[c]	c	c	c	c
Pd-103 implant	1.5	40	0.03	3
Re-186	28	770	0.15	15
Re-188	29	790	0.20	20
Sc-47	11	310	0.17	17
Se-75	0.089	2	0.005	0.5
Sm-153	26	700	0.3	30
Sn-117m	1.1	29	0.04	4
Sr-89[c]	c	c	c	c
Tc-99m	28	760	0.58	58
T1-201	16	430	0.19	19
Yb-169	0.37	10	0.02	2

a.	The activity values were computed based on 5-mSv (0.5 rem) total effective dose equivalent.
b.	If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record as required by 10 CFR 35.75(c), because the measurement includes shielding by tissue. See Staff Regulatory Guidance3.1, "Records of Release," for information on records.
c.	Activity and dose rate limits do not apply to these radionuclides because of the minimal exposures to members of the public resulting from dosages normally administered for diagnostic or therapeutic purposes.

Notes:

The millicurie (mCi) values in Table 1 were calculated using Equation 2 or 3 and the physical half-life. The gigabecquerel (GBq) values were calculated based on the mCi values and the conversion factor from mCi to GBq. The dose rate values were calculated based on the mCi values and the exposure rate constants. In general, the values were rounded to two significant figures. However, values less than 0.37 GBq (10 mCi) or 0.1 mSv (10 millirem (mrem)) per hour were rounded to one significant figure. NUREG-1492 describes the calculations in detail. Agreement State regulations may vary. Agreement State licensees should check their State regulations before using these values.
