Hicon® (Sodium Iodide I - 131)
(Oral)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for one administration of Hicon.
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- Hyperthyroidism
  - Up to 10 billable units (370 mBq; 10 mCi) per administration
- Thyroid Carcinoma
  - Up to 200 billable units (7400 mBq; 200 mCi) per administration

III. Initial Approval Criteria [1,3-7]

Prior authorization validity is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Females of reproductive potential have a negative pregnancy test prior to treatment; **AND**
- Lactating women should discontinue breast feeding at least 6 weeks prior to administration; **AND**
- Patient has adhered to a low-iodide diet for at least two weeks prior to therapy; **AND**
- Patient has discontinued any anti-thyroid medication (e.g., methimazole, propylthiouracil, triiodothyronine, thyroxine, etc.) for at least three days prior to therapy; **AND**
- Patient is not currently experiencing vomiting and/or diarrhea; **AND**
- Patients with thyroid malignancies (e.g., medullary or anaplastic carcinomas) must demonstrate iodide uptake; **AND**

Hyperthyroidism † [1,4]

- Other causes of hyperthyroidism have been ruled out (e.g., thyroid malignancy, TSH-secreting pituitary tumors, etc.); **AND**
  - Patient has a confirmed diagnosis of hyperthyroidism related to Grave's Disease; **AND**

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        - Patient has failed or has intolerance or contraindication to anti-thyroid medication therapy; **OR**
    - Patient has a confirmed diagnosis of hyperthyroidism related to toxic nodular/multinodular goiter or toxic adenoma

Thyroid Carcinoma † ‡ [1,3,5,7]

- Patient has a diagnosis of Follicular, Papillary, or Oncocytic Carcinoma; **AND**
    - Patient had a thyroidectomy; **OR**
    - Patient has locoregional recurrence OR metastatic disease

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria

Duration of authorization has not been exceeded *(refer to Section I)*

V. Dosage/Administration

Indication	Dose
Hyperthyroidism	Administer 148 to 370 MBq (4 to 10 mCi) orally. Toxic nodular goiter may require a larger dose.
Thyroid Carcinoma	Administer 1100 to 3700 MBq (30 to 100 mCi) orally. For subsequent ablation of metastases, the recommended dose is 3700 to 7400 MBq (100 to 200 mCi) administered orally. **Note: Radiation dosimetry is the preferred dosing standard.*
Individualization of Therapy The recommended dose for orally administered sodium iodide I 131 capsules or solution is based on the thyroid gland uptake as well as the size of the gland. Thyroidal uptake and size should be determined by the physician prior to treatment and may be useful in calculating the therapeutic dose to be administered to the individual patient.	
– *Hicon is a radioactive drug. Handle with appropriate safety measures to minimize radiation exposure to the patient and healthcare workers. Use only by, or under the direction of, physicians who are qualified by specific training and experience in the safe use and handling of radioactive materials, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radiopharmaceuticals.*	

VI. Billing Code/Availability Information

HCPCS Code(s):

- A9517 – Iodine i-131 sodium iodide capsule(s), therapeutic, per millicurie; 1 billable unit = 1 mCi

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- A9530 – Iodine i-131 sodium iodide solution, therapeutic, per millicurie; 1 billable unit = 1 mCi

NDC(s):

- Hicon 9,250 MBq (250 mCi); 18,500 MBq (500 mCi); and 37,000 MBq (1,000 mCi) in 1 mL clear vials*: 65174-0880-XX

Notes:

- *A minimum of one blister package of 10 empty large hard gelatin capsules and a minimum of one blister package of 10 small hard gelatin capsules containing approximately 300 mg of dibasic sodium phosphate anhydrous as the absorbing buffer are supplied along with Hicon for the preparation of sodium iodide I 131 capsules, therapeutic.*
- *The concentrated solution is intended for use in the preparation of capsules and solutions of varying strengths for oral administration.*
- *As a radiopharmaceutical, formulation availability may vary.*

VII. References

1. Hicon [package insert]. Kirkland, Quèbec, Canada; Jubilant DraxImage Inc.; January 2025. Accessed September 2025.
2. Van Nostrand D. I131 ablation and treatment in well differentiated thyroid cancer. In: Van Nostrand D, Bloom G, Wartofsky L, Kulkarni KP, eds. *Thyroid Cancer*: *A Guide for Patients*. Pasadena, MD: Keystone Press; 2004;201-203.
3. Van Nostrand D. The Benefits and Risks of I-131 Therapy in Patients with Well-Differentiated Thyroid Cancer. Thyroid, 2009.VOL. 19, NO. 12.
4. Ross DS, Burch H, Cooper DS, et al. 2016 American Thyroid Association Guidelines for Diagnosis and Management of Hyperthyroidism and other causes of Thyrotoxicosis. Thyroid. 2016.
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Thyroid Carcinoma. Version 1.2025. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed September 2025.
6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Sodium Iodide I 131. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are

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trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed September 2025.

7. American College of Radiology (ACR), American College of Nuclear Medicine (ACNM), American Society for Radiation Oncology (ASTRO), Society of Nuclear Medicine and Molecular Imaging (SNMMI), and Society for Pediatric Radiology (SPR). ACR–ACNM–ASTRO–SNMMI–SPR Practice Parameter for Treatment of Benign and Malignant Thyroid Disease with I-131 sodium iodide. [online publication]. Reston, VA: American College of Radiology (ACR); Adopted 2019 (Resolution 37); Revised 2024 (Resolution 12). https://gravitas.acr.org/PPTS/GetDocumentView?docId=29

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C73	Malignant neoplasm of the thyroid gland
E05.00	Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm
E05.01	Thyrotoxicosis with diffuse goiter with thyrotoxic crisis or storm
E05.10	Thyrotoxicosis with toxic single thyroid nodule without thyrotoxic crisis or storm
E05.11	Thyrotoxicosis with toxic single thyroid nodule with thyrotoxic crisis or storm
E05.20	Thyrotoxicosis with toxic multinodular goiter without thyrotoxic crisis or storm
E05.21	Thyrotoxicosis with toxic multinodular goiter with thyrotoxic crisis or storm

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ICD-10	ICD-10 Description
Z85.850	Personal history of malignant neoplasm of thyroid

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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