

Hicon® (Sodium Iodide I - 131) (Oral)

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I. Length of Authorization

Coverage will be provided for one administration of Hicon and cannot be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- N/A

B. 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 ¹⁻⁷

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Women of child-bearing age must 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**
- Patients of reproductive potential must use effective contraception during treatment with therapy and for at least six months after the last dose; **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**
 - 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 † ‡^{1,2,3,5,7}

- Patient has a diagnosis of follicular, papillary, or oncocytic carcinoma; **AND**
 - Patient had a thyroidectomy; **OR**
 - Patient has locoregional, metastatic, or recurrent disease

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

IV. Renewal Criteria

Coverage cannot be renewed.

V. Dosage/Administration

Indication	Dose
Hyperthyroidism	The recommended dose is 148 to 370 MBq (4 to 10 mCi) administered orally. Toxic nodular goiter may require a larger dose.
Thyroid Carcinoma	The recommended dose is 1100 to 3700 MBq (30 to 100 mCi) administered orally. For subsequent ablation of metastases, the recommended dose is 3700 to 7400 MBq (100 to 200 mCi) administered orally. <i>*Note: Radiation dosimetry is the preferred dosing standard.</i>
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.	
– <i>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.</i>	

VI. Billing Code/Availability Information

HCPCS Code:

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

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

**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.*

VII. References

1. Hicon [package insert]. Kirkland, Québec, Canada; Jubilant DraxImage, Inc.; November 2021. Accessed May 2023.
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 2.2023. National Comprehensive Cancer Network, 2023. 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 May 2023.
6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Sodium Iodide I 131. National Comprehensive Cancer Network, 2023. 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 May 2023.
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). <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/I131SodiumIodide.pdf>

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

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

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 Determination (NCD), Local Coverage Article (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered 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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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