

Hicon® (Sodium Iodide I - 131)

Policy Number: **M20200508035**
 Effective Date: **7/1/2020**
 Sponsoring Department: **Health Care Services**
 Impacted Department(s): **Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐ Confidential ☐ Restricted ☒ Public

Applies to (Line of Business):

- ☐ Corporate (All)
- ☒ State Products, if yes which plan(s): ☒ MediSource; ☒ MediSource Connect; ☒ Child Health Plus; ☒ Essential Plan
- ☒ Medicare, if yes, which plan(s): ☒ MAPD; ☐ PDP; ☒ ISNP; ☒ CSNP
- ☒ Commercial, if yes, which type: ☒ Large Group; ☒ Small Group; ☒ Individual
- ☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No ☒

Purpose and Applicability:

To set forth medical necessity criteria for **Hicon®** for **hyperthyroidism** and differentiated thyroid carcinoma.

Policy:

Background: Radioactive iodine (I-131), an isotope of iodine that emits radiation that when swallowed in a single dose in either liquid or capsule form, is absorbed into the bloodstream in the gastrointestinal (GI) tract and concentrated from the blood by the thyroid gland, where it begins destroying the gland's cells.

Hyperthyroidism is an excessive concentration of thyroid hormones in tissues. Common endogenous causes of hyperthyroidism are Graves' disease, toxic multinodular goiter, toxic adenoma, and painless thyroiditis, with Graves' disease as the most common cause. Radioactive iodine ablation of the thyroid gland is the most common treatment of Graves' disease in the United States.

Thyroid cancer is generally divided into two categories. The first category is differentiated thyroid cancer, which includes well-differentiated tumors, poorly differentiated tumors, and undifferentiated tumors (papillary, follicular, or anaplastic). The second category is medullary thyroid cancer. Standard treatment options for localized/regional papillary and follicular thyroid cancer include: total thyroidectomy, lobectomy, radioactive iodine (RAI) therapy, thyroid-suppression therapy, and external-beam radiation therapy (EBRT).

Most patients develop permanent hypothyroidism between two and six months after radioactive iodine ablation and require ongoing thyroid hormone supplementation. Patient restrictions prior to treatment include the discontinuation of anti-thyroid medications three days prior to therapy, commencement of low-iodide diet at least two weeks prior to therapy, discontinuation of breast feeding, and a negative pregnancy test for females. It is recommended that pregnancy be delayed until at least 6 to 12 months after I-131 treatment.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined below.

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

Commercial, Self-Funded, Medicare Advantage, MediSource, MediSource Connect, Child Health Plus, Essential Plan: Hicon is covered utilizing the criteria below.

Clinical Indications:

Coverage will be provided for one (1) administration of Hicon for **ALL** of the following:

- **1 or more** of the following indications:
 - Hyperthyroidism and **ALL** of the following (Up to 10 billable units (370 mBq; 10 mCi) per administration):
 - Other causes of hyperthyroidism have been ruled out (e.g., thyroid malignancy, TSH-secreting pituitary tumors, etc.) and **1 or more** of the following:
 - Member has a confirmed diagnosis of hyperthyroidism related to Graves' Disease and **1 or more** of the following:
 - ✓ Member has failed or has intolerance or contraindication to anti-thyroid medication therapy
 - Member has a confirmed diagnosis of hyperthyroidism related to toxic nodular/multinodular goiter or toxic adenoma
 - Differentiated Thyroid Carcinoma (DTC) and **ALL** of the following (Up to 200 billable units (7400 mBq; 200 mCi) per administration):
 - Member has a diagnosis of follicular or papillary thyroid carcinoma
 - Member has proven or suspected radio-iodine uptake of the thyroid bed or tumor and **1 or more** of the following:
 - Therapy will be used for adjuvant (post-surgical) radioactive iodine (RAI) ablation in members who have had a thyroidectomy

- Treatment of locoregional, metastatic, or recurrent DTC
- **ALL** of the following initial approval criteria:
 - Member is 18 years or older
 - If the member is of childbearing age they must have a negative pregnancy test prior to treatment
 - If member is lactating or breastfeeding, then discontinue breast feeding at least 6 weeks prior to administration
 - Member has adhered to a low-iodide diet for at least two weeks prior to therapy
 - If member is taking anti-thyroid medication then discontinue all anti-thyroid medication (e.g., methimazole, propylthiouracil, triiodothyronine, thyroxine, etc.) for at least three days prior to therapy
 - If member has reproductive potential they are counseled on using effective contraception during treatment with therapy and for at least six months after the last dose
 - Member is not currently experiencing vomiting and/or diarrhea

Pre-Authorization Required? Yes ☐ No ☒

Pre-authorization is required for this service.

Definitions

Hicon® (Sodium Iodide I - 131): a radioactive therapeutic agent indicated for the treatment of hyperthyroidism and selected cases of carcinoma of the thyroid.

Hyperthyroidism(overactive thyroid): occurs when the thyroid gland produces too much of the hormone thyroxine, increasing the body's metabolism, causing unintentional weight loss and arrhythmias.

References

Related Policies, Processes and Other Documents

N/A

Non-Regulatory references

American College of Radiology (ACR) [web site]. ACR–ACNM–ARS–SNMMI–SPR Practice Parameter for Treatment of Benign and Malignant Thyroid Disease with I-131 Sodium Iodide. Adopted 2019 (Resolution 37), Revised 2024 (Resolution 12). Available at:<https://gravitas.acr.org/PPTS/DownloadPreviewDocument?ReleaseId=2&DocId=29> Accessed March 24, 2026.

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Regulatory References

New York State Department of Health [web site]. New York State Medicaid Program Section 4 Radiology. April 2025.. Available at: <https://www.emedny.org/ProviderManuals/Physician/PDFS/Physician%20Procedure%20Codes%20Section%204.pdf> Accessed February 6, 2026.

United States Food and Drug Administration (FDA) [web site]. Approved Labeling Sodium Iodide I - 131) Capsules and Solution USP Therapeutic- Oral. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/21-305_Sodium%20Iodide_Prntlbl.pdf Accessed February 6, 2026.

United States Food and Drug Administration (FDA) [web site]. Approved Labeling Sodium Iodide I - 131) Capsules and Solution USP Diagnostic- Oral. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/021305s042lbl.pdf Accessed February 6, 2026.

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No ☐

Revision Date	Owner	Notes
6/1/2026	Health Care Services	Revised
8/1/2025	Health Care Services	Revised- Formatting only
6/1/2025	Health Care Services	Reviewed
6/1/2024	Health Care Services	Revised
1/1/2024	Health Care Services	Reviewed
6/1/2023	Health Care Services	Reviewed
6/1/2022	Health Care Services	Reviewed
6/1/2021	Health Care Services	Reviewed