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:

Commercial, Self-Funding, and Medicare Advantage:

Initial Approval Criteria:

- Patient is 18 years or older; 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
- Coverage is provided in the following conditions**:**

1. Hyperthyroidism
   - 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.

2. Differentiated Thyroid Carcinoma (DTC)
   - Patient has a diagnosis of follicular or papillary thyroid carcinoma; AND
   - Patient has proven or suspected radio-iodine uptake of the thyroid bed or tumor; AND
   - Therapy will be used for adjuvant (post-surgical) radioactive iodine (RAI) ablation in patients who have had a thyroidectomy; OR
   - Treatment of locoregional, metastatic, or recurrent DTC

Dosage:

1. Hyperthyroidism
   - Up to 10 billable units (370 mBq; 10 mCi) per administration

2. Thyroid Carcinoma
   - Up to 200 billable units (7400 mBq; 200mCi) per administration

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

MediSource, MediSource Connect, Essential Plan:
MediSource, MediSource Connect, and Essential Plan cover Hicon® utilizing the Commercial criteria above.

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 the following two categories. The first category differentiated thyroid cancer, which includes well-differentiated tumors, poorly differentiated tumors, and undifferentiated tumors (papillary, follicular, or anaplastic) and the second category, medullary thyroid cancer. Standard treatment options for localized/regional papillary and follicular thyroid cancer include the following: 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, commencement of low-iodide diet for 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 six 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 above.

Pre-Authorization Required? Yes ☒ No ☐

Pre-authorization is required for this service.

Definitions

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

Hyperthyroidism, or 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–ASTRO–SNMMI–SPR Practice Parameter for Treatment of Benign and Malignant Thyroid Disease with I-131 Sodium Iodide. Adopted 2019 (Resolution 37). Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/I131SodiumIodide.pdf Accessed March 28, 2023

Haugen BR, Alexander EK, Bible KC, et al. 2015 American Thyroid Association Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer: The American Thyroid Association Guidelines Task Force on Thyroid Nodules and Differentiated Thyroid Cancer. Thyroid. 2016 Jan;26(1):1-133.

Kravets I. Hyperthyroidism: Diagnosis and Treatment. Am Fam Physician. 2016 Mar 1;93(5):363-70.

Lexicomp. Sodium iodide I-131: Drug information. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed on March 28, 2023.

National Cancer Institute (NCI) [web site]. Thyroid Cancer Treatment (Adult) (PDQ®)–Health Professional Version. Updated February 16, 2023. Available at: https://www.cancer.gov/types/thyroid/hp/thyroid-treatment-pdq#link/_920 Accessed March 28, 2023

National Comprehensive Cancer Network (NCCN) [web site]. Thyroid Carcinoma Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf Accessed March 28, 2023

Padma S, Sundaram PS. Radioiodine as an adjuvant therapy and its role in follow-up of differentiated thyroid cancer. J Cancer Res Ther. 2016 Jul-Sep;12(3):1109-1113.

Radiological Society of North America, Inc. (RSNA) [web site]. Radioactive Iodine (I-131) Therapy. Updated November 1, 2022. Available at: https://www.radiologyinfo.org/en/info.cfm?pg=radioiodine Accessed March 28, 2023

Ross Ds. Radioiodine in the treatment of hyperthyroidism. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed on March 28, 2023

Ross DS, Burch HB, Cooper DS et al. 2016 American Thyroid Association Guidelines for Diagnosis and Management of Hyperthyroidism and Other Causes of Thyrotoxicosis. Thyroid. 2016 Oct;26(10):1343-1421.

Regulatory References

New York State Department of Health [web site]. New York State Medicaid Program Section 4 Radiology. Version 2022-2. Available at: https://www.emedny.org/ProviderManuals/Physician/PDFS/Physician%20Procedure%20Codes%20Sect4.pdf Accessed March 28, 2023

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 March 28, 2023

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 March 28, 2023

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
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