Sodium Iodide-131 Policy

Purpose

To describe the CVS Radiation Oncology Policy for HICON (sodium iodide 131).

Scope

The scope of this document applies to CVS Health® clients who have signed up for the CVS Radiation Oncology program under CVS Health Solutions. This document includes the policy details for the HICON (sodium iodide 131) policy.

Policy

HICON (sodium iodide 131) Policy

I.Criteria for Initial Approval

A. Hyperthyroidism

CVS Health considers sodium iodide-131 medically necessary for the treatment of hyperthyroidism.

B. Thyroid carcinoma

CVS Health considers sodium iodide-131 medically necessary for treatment of thyroid carcinoma for members when all of the criteria are met:

1. Member has a diagnosis of papillary, follicular, or oncocytic thyroid carcinoma; AND

- a. Member had a thyroidectomy; OR
- b. Member has locoregional, metastatic, or recurrent disease

CVS Health considers all other indications as experimental and investigational (for additional information, see Experimental and Investigational and Background sections).

II. Continuation of Therapy

See Dosage and Administration information.

Procedure

Dosage and Administration

HICON (sodium iodide-131) is available as a concentrated solution of sodium iodide I 131 with a radioconcentration of 37,000 MBq/mL (1,000 mCi/mL). It is supplied in 1 mL clear vials that contain approximately 9,250 MBq (250 mCi), 18,500 MBq (500 mCi), and 37,000 MBq (1,000 mCi) at the time of calibration. The concentrated solution is intended for use in the preparation of capsules and solutions of varying strengths for oral administration.

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.

<u>Treatment of Hyperthyroidism</u> The recommended dose is 148 MBq to 370 MBq (4 mCi to 10 mCi) administered orally. Toxic nodular goiter may require a larger dose.

<u>Treatment of Thyroid Carcinoma</u> The recommended dose is 1,100 MBq to 3,700 MBq (30 mCi to 100 mCi) administered orally. For subsequent ablation of metastases, the recommended dose is 3,700 MBq to 7,400 MBq (100 mCi to 200 mCi) administered orally.

Experimental and Investigational

CVS Health considers the use of sodium iodide 131 experimental and investigational for all other indications not listed above because its effectiveness for these indications have not been established.

References

The sodium iodide-131 policy is based on the following references:

- 1. HICON (sodium iodide-131) injection, for intravenous use. Prescribing Information. Jubilant Pharmaceuticals, Inc. Kirkland, Quebec Canada; revised June 2021.
- 2. National Comprehensive Cancer Network (NCCN). Sodium Iodide-131. NCCN Drugs & Biologics Compendium. Accessed July 29th, 2024.