Dear Healthcare Provider:

The Voutia™ System is available for purchase directly to consumers through our website. However, if you are recommending this device and if your patient has concerns regarding insurance participation, please refer to the following recommendations:

1. **FSA funding** can be obtained by referring to the HSA/FSA tab on the website. Print and complete the form under this tab and give it to your patient. *Your patient will then need to present this form their policy administrator at their place of employment.*
2. **HSA funding** can be obtained by referring to the HSA/FSA tab on our web site (Voutia.com). Print and complete the form under this tab and give it to your patient. *Your patient should keep this form with their sales receipt for the device. No submission is necessary*.
3. **Insurance participation** will be initiated by having your office submit the claim with an unspecified DME code:
    - **A9999** Miscellaneous DME supply or accessory, not otherwise specified
    - **E1399** Durable medical equipment, miscellaneous

    Specific insurance coverage
    Individual claims will be decided on a case by case basis by each carrier company. One of these codes should be filed to insurance with a detailed description of the system (see below) including the indicated use as it is an unspecified code.

    A **letter of medical necessity** sent to the insurance provider should further clarify your patient's needs and how Voutia™ would benefit your patient. This form can be found on our website Voutia.com/Healthcare-professionals or attached below.

If you have any questions, please contact us. We are always interested in learning about successes and/or frustrations with this process.

Sincerely,

The Voutia™ Team

For more information, go to our website at VOUTIA.COM.

If you prefer a phone call or a Zoom meeting, please contact us on 804.803.1840 to set up an appointment.

COMING SOON: Website financing options and our new Facebook page!

The Voutia™ System
Detailed Device Description

The Voutia™ System Overview

The Voutia™ System is a new FDA cleared (K173808, July 2018), over the counter device that is designed to treat individuals suffering from an actual or perceived deficiency in oral saliva production. Voutia's™ statement of intended use as filed with the U.S. Food and Drug Administration is as follows:

> **Indications for use:**
> *The Voutia™ system is indicated to provide relief of acute or chronic dry mouth by coating, moistening, and lubricating oral structures thereby relieving the symptoms of xerostomia (dry mouth). It is intended for use in individuals suffering from a deficiency in saliva production as a result of numerous medical conditions, treatments and medicines, as well as damage and/or destruction of salivary gland tissue secondary to head and neck radiation treatment prescribed for the management and eradication of cancer who do not have a known impairment of the swallowing or gag reflex as determined by their treating physician.*

Description of the Voutia™ System's Components

The Voutia™ system is a programmable computer board (PCB) controlled intraoral fluid delivery system. It consists of 3 main parts:

1. Reservoir: A container to house the fluid for delivery.
2. Pump and control system: Injection molded, dual chambered housing with an internal rechargeable power supply, LCD display, PCB board, inlet and outlet ports, membrane touchpad, and pump. Electronics are sequestered in a second gasket lined chamber and protected from moisture ingress.
3. Headset: ear mounted or adhesive secured medical grade tubing attached to a soft silicone ear support.

Purpose of the Voutia™ System:

The Voutia™ system has been designed to treat acute or chronic dry mouth symptoms by delivering potable water directly to the oral cavity. It does so in a hands-free manner with user adjustable flow rates. The flow rates are intended to mimic those of the normal human saliva secretion rates corresponding to human circadian rhythm patterns. It has been designed and tested to be used at any time of the day, including during sleep.

How is it the Voutia™ System utilized?

The system is designed to be easy to use and user friendly. The basic process for utilization is as follows (also see Figs 2-9 below):

1. Users fill the reservoir with the potable water.
2. The reservoir is attached to the marked "in" port on the pump housing.

3. The headset is placed on a user's ear or affixed with hypoallergenic medical tape and the micro-tube is inserted into the mouth and positioned where comfortable.
4. The other end of the headset is attached to the pump housing's marked "out" port.
5. Users activate the unit and select the rate of fluid deposition to meet their specific needs. Fluid delivery rates range from 0.1 ml/min to 0.9 ml/min (adjustable in 0.1 ml/min increments). Users are instructed in the accompanying manual to not exceed 0.3 ml/min during sleep use.
6. The Voutia™ system will begin delivering reservoir contents at the selected rate directly to the oral cavity until the battery is exhausted or the user turns off/pauses the unit. Flow rates may be adjusted at any time during use.
7. The Voutia™ System has 4 programmable modes: Sleep, Sitting, Day, and Exercise. When selected, each mode can be set to a user desired flow rate and the device will store this flow rate for future use.

Capabilities:

1. Directly deliver potable water to the oral cavity for immediate and continuous relief of xerostomia symptoms
2. Fluid delivery can be directed to specific locations in the oral cavity
3. Nine user adjustable flow rates from 0.1 ml/min to 0.9 ml/min (9 levels increasing or decreasing flow by 0.1 ml/min for each level.)
4. May be used while sleeping: Beta tested for over 4 years to show proof of concept and the ability to use while sleeping. No adverse events reported to date.
5. May be used powered by the rechargeable internal battery or powered from a standard outlet while charging.

Contraindications:

The Voutia™ system is contraindicated for patients with a damaged or impaired swallow reflex or who have failed a physician prescribed swallow test.

Virginia Head and Neck Therapeutics, Inc.
10149 Bon Air Crest Dr.
Richmond, VA, 23235

Certificate of Medical Necessity

Patient Name, Address, Telephone and HICN

(_ _ _) _ _ _-_ _ _ _ HINC:_____

Supplier Name, Address, Telephone and NSC or NPI#

(_ _ _) _ _ _-_ _ _ _ NSC or NPI #:_____

PT DOB ___/___/____; Sex:_____ ; HT._____ ; WT. _____ (lbs)

Place of Service _____ Name and address of facility if applicable	HCPCS CODE _____ _____ _____ _____ _____	Physician's name, Address (printed/typed) Physician's NSC or NPI #:_____ Physician's Telephone #: (_ _ _) _ _ _- _ _ _ _

SECTION B: Information in this section may not by the supplier of the items/supplies.

EST. LENGTH OF NEED (# OF MONTHS): _____ 1-99(99=LIFETIME)	Diagnosis Codes: _____ _____ _____

Answers	Answer questions 1-2 for initial evaluation Answer questions 3-4 for follow up evaluation (recertification) Circle Y for YES, N for NO, D for DOES NOT APPLY
Y / N / D	1. Is the device being ordered for the treatment of Xerostomia?
___/___/_____	2. Enter the date of the initial consultation.
___/___/_____	3. Enter the date of the follow up face to face consultation.
Y / N / D	4. Did the patient demonstrate/report improvement in symptoms of xerostomia?

Name of person answering these questions if other than the Physician/Dentist (Please Print)
Name:_____ Title:_____ Employer:

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Richmond, VA, 23235

SECTION C: NARRATIVE DESCRIPTION OF EQUIPMENT AND COST

(1) Narrative description of all items, accessories, and options ordered; **(2)** Supplier's Charge; and **(3)** Medicare fee schedule allowance for each item, accessory, and option.

SECTION D: PHYSICIAN ATTESTATION AND SIGNATURE/DATE:
I certify that I am the Physician/Dentist identified in section A of this form. I have received sections A, B, and C of the Certificate of Medical Necessity (including charges for items ordered). Any statement on my letterhead attached hereto, has been reviewed and signed by me. I certify that the medical necessity information in Section B is true, accurate, and complete to the best of my knowledge, and I understand that any falsification, omission, or concealment of material or fact in that section may subject me to civil or criminal liability.

Physician/Dentist's Signature_____ Date: ___ /___ / _____
(Stamps not acceptable)