

**Subject:** Self-Expanding Absorptive Sinus Ostial Dilation**Document #:** SURG.00089**Status:** Reviewed**Publish Date:** 04/10/2024**Last Review Date:** 02/15/2024

## Description/Scope

This document addresses the use of self-expanding absorptive sinus ostial dilation for the treatment of sinusitis. This procedure involves insertion of a self-expanding absorptive device (for example, the SinuSys Vent-OS™ device) into a nasal sinus cavity to open blocked sinus ostia.

For additional information regarding treatment of rhinosinusitis, please see:

- [CG-SURG-18 Septoplasty](#)
- [CG-SURG-24 Functional Endoscopic Sinus Surgery \(FESS\)](#)
- [CG-SURG-57 Diagnostic Nasal Endoscopy](#)
- [CG-SURG-73 Balloon Sinus Ostial Dilation](#)
- [MED.00091 Rhinophototherapy](#)
- [SURG.00132 Drug-Eluting Devices for Maintaining Sinus Ostial Patency](#)

## Position Statement

### Investigational and Not Medically Necessary:

The use of self-expanding absorptive sinus ostial dilation for the treatment of *any* sinus condition, including, but not limited to sinusitis, is considered **investigational and not medically necessary**.

## Rationale

In early 2014, the U.S. Food and Drug Administration (FDA) granted 510k clearance to the SinuSys Vent-OS Sinus Dilation System for dilation of the maxillary sinus ostia and associated spaces in adults. There are no full-text published studies in the peer-reviewed literature addressing this device. At this time, there is insufficient evidence to permit reasonable conclusions concerning the effect of this device on net health outcomes.

Furthermore, while there are multiple guidelines, recommendations, and consensus statements regarding the treatment of rhinosinusitis from authoritative organizations such as the American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) and the American Rhinologic Society (ARS), these documents do not mention the SinuSys Vent-OS device.

## Background/Overview

Chronic sinusitis is defined as a prolonged or recurrent infection and inflammation of the nasal sinuses. Nasal sinuses are open spaces in the head connected by small passageways to the nasal passageways leading from the nose. Under normal conditions, air passes in and out of the sinuses, and mucus and fluid drain from the sinuses into the nose.

Sinusitis occurs when there is infection or inflammation in one or more of the sinuses. Temporary or acute sinusitis is often associated with upper respiratory infections or irritation due to allergic reactions which cause temporary blockage of the passages leading from the sinuses. Blocked sinuses can accumulate nasal secretions and bacteria, leading to infection.

Chronic, long-term sinusitis may develop in people with chronic allergies, deviated nasal septum or other obstruction of the nose. Additionally, dental infections such as tooth abscesses may also spread into the sinus and infect it directly.

When sinusitis recurs frequently, or lasts for a prolonged period, it is classified as chronic. While acute sinusitis is usually caused by infection with a single type of bacteria or virus, chronic sinusitis is usually caused either by allergies or by infection with a mixture of different types of bacteria.

Chronic sinusitis may have less severe symptoms than acute sinusitis but can cause damage and destruction to the tissues of the sinuses. It may flare up spontaneously or may follow respiratory infections such as colds.

Treatment of chronic sinusitis usually involves the use of antibiotics if the infection is bacterial. Oral sinus decongestants are sometimes used as well. In more serious cases related to allergies, topical steroids in the form of nasal sprays may be helpful in controlling inflammation. Surgery to clean and drain the sinuses may be necessary to clear serious chronic infections. Finally, surgical repair of a deviated nasal septum or other nasal obstruction may prevent recurrence of chronic sinusitis.

Sinus surgery is commonly done with the use of thin fiberoptic tools that are passed through the nostrils. This method, referred to as endoscopic sinus surgery, allows visualization and manipulation of the surgical site without the need for surgical incisions in the mouth or face. Once the endoscopic tools are in place in the surgical site, small tools are used to obliterate the sinus tissue and bone to open the sinus passages.

A technique proposed as an alternative to standard endoscopic surgery is referred to as self-expanding absorptive sinus ostial dilation. This procedure involves the intranasal insertion of a plug-like device into the sinus ostia. Once inserted, the device absorbs moisture from the surrounding tissue and begins to expand, providing low-pressure, gradual dilation of the sinus ostia. Once the device has been given enough time to fully expand, it is removed. This type of device is proposed to maximize patient tolerability of the procedure; however, such claims have yet to be fully evaluated.

## Coding

*The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider*

reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

**When services are Investigational and Not Medically Necessary:**

**CPT**

31299

Unlisted procedure, accessory sinuses [when specified as application of self-expanding absorptive sinus ostial dilator (for example, SinuSys Vent-OS Sinus Dilation System)]

**ICD-10 Diagnosis**

All diagnoses

## References

**Government Agency, Medical Society, and Other Authoritative Publications:**

1. American Academy of Otolaryngology - Head and Neck Surgery. Dilation of sinuses, any method (e.g., balloon, etc.). Adopted June 16, 2010. Revised April 13, 2021. Available at: <https://www.entnet.org/resource/position-statement-dilation-of-sinuses-any-method-e-g-balloon-etc/>. Accessed on February 1, 2024.
2. American Rhinologic Society. Ostial balloon dilation position statement. January 28, 2023. Available at: [https://www.american-rhinologic.org/index.php?option=com\\_content&view=article&id=494:ostial-balloon-dilation-position-statement&catid=26:position-statements&Itemid=197](https://www.american-rhinologic.org/index.php?option=com_content&view=article&id=494:ostial-balloon-dilation-position-statement&catid=26:position-statements&Itemid=197). Accessed on December 6, 2023.
3. Piccirillo JF, Payne SC, Rosenfeld RM, et al. Clinical consensus statement: balloon dilation of the sinuses. Otolaryngol Head Neck Surg. 2018; 158(2):203-214.
4. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (Update): Adult Sinusitis. Otolaryngol Head Neck Surg. 2007; 152(4):598-609.

## Websites for Additional Information

1. National Library of Medicine. Medical Encyclopedia. Sinusitis. Available at: <http://www.nlm.nih.gov/medlineplus/ency/article/000647.htm>. Accessed on February 1, 2024.

## Index

Vent-OS Sinus Dilation System

**The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.**

## Document History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised References and Websites sections.
Reviewed	02/16/2023	MPTAC review. Updated References and Websites sections.
Reviewed	02/17/2022	MPTAC review. Updated References and Websites sections.
Reviewed	02/11/2021	MPTAC review. Updated References and Websites sections.
Reviewed	02/20/2020	MPTAC review. Updated References and Websites sections.
Reviewed	03/21/2019	MPTAC review. Updated References section.
Revised	03/22/2018	MPTAC review. Revised title and content of document to focus on self-expanding absorptive sinus Ostial dilation. Updated Description/Scope, Rationale, Background/Overview, Coding, References, and Index sections.
Revised	11/02/2017	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Revised position statement to consider balloon sinus ostial dilation MN with criteria. Updated Rationale and References sections. Updated Coding section to include 01/01/2018 CPT changes.
Reviewed	05/04/2017	MPTAC review. Updated Rationale and References sections.
Reviewed	05/05/2016	MPTAC review. Updated Rationale and Reference sections. Removed ICD-9 codes from Coding section.
Reviewed	05/07/2015	MPTAC review. Updated Rationale and Reference sections.
Reviewed	05/15/2014	MPTAC review. Updated Rationale and Reference sections.
Revised	02/13/2014	MPTAC review. Revised title and position statement to add "and self-expanding absorptive". Updated Rationale and Background sections.
Reviewed	11/14/2013	MPTAC review. Updated Rationale and Reference sections.
Reviewed	08/08/2013	MPTAC review. Updated Rationale, Reference, and Index sections.
Reviewed	02/14/2013	MPTAC review. Updated Rationale and Reference sections.
Reviewed	02/16/2012	MPTAC review. Updated Rationale and Reference sections.
Reviewed	05/19/2011	MPTAC review. Revised title from "Balloon Sinuplasty" to "Balloon Sinus Ostial Dilation". Revised "balloon sinuplasty" to "balloon sinus ostial dilation" throughout document where appropriate. Updated Rationale section.
	04/01/2011	Updated Coding section with 04/01/2011 HCPCS changes; removed S2344 deleted 03/31/2011.
Reviewed	11/18/2010	MPTAC review. Updated Rationale and Reference sections. Updated Coding section with 01/01/2011 CPT changes.
Reviewed	11/19/2009	MPTAC review. Updated Rationale and Reference sections.
Reviewed	11/20/2008	MPTAC review. Updated Rationale and Reference sections.
Reviewed	02/21/2008	MPTAC review. The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Reviewed	03/08/2007	MPTAC review. Updated Reference section.
	01/01/2007	Updated Coding section with 01/01/2007 CPT/HCPCS changes.
New	09/14/2006	MPTAC initial document development.

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