

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>BALLOON OSTIAL DILATION FOR THE TREATMENT OF CHRONIC RHINOSINUSITIS AND RECURRENT ACUTE RHINOSINUSITIS</b>
<b>POLICY NUMBER</b>	<b>MP 1.119</b>

<b>CLINICAL BENEFIT</b>	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input checked="" type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
<b>Effective date:</b>	<b>6/1/2026</b>

### POLICY

Use of a catheter-based inflatable device (balloon ostial dilation) for the treatment of chronic rhinosinusitis in the sinus being considered for dilation may be **medically necessary** when the following criteria are present:

- Individual is 18 years of age or older (see Policy Guidelines for younger ages); **and**
- Chronic rhinosinusitis without nasal polyps that negatively impacts quality of life, characterized by at least 2 of the following, at least 1 of which is (a) or (b), present for at least 12 continuous weeks:
  - a. Mucopurulent nasal drainage (anterior, posterior, or both);
  - b. Nasal obstruction (congestion);
  - c. Facial pain-pressure-fullness;
  - d. Decreased sense of smell. **and**
- Optimal medical therapy has been attempted and failed, as indicated by all of the following:
  - Allergy evaluation, education, and optimal treatment when indicated;
  - Two 10-day courses of antibiotics, or 1 prolonged course of at least 21 days duration;
  - Decongestants when indicated;
  - Topical and/or systemic corticosteroids for at least 8 weeks;
  - Saline nasal irrigation for at least 8 consecutive weeks;
  - Treatment of rhinitis medicamentosa (rebound nasal congestion due to extended use of topical decongestants), when present;
  - Education on environmental irritants including tobacco smoke; **and**
- Clinical and radiographic documentation of persistent inflammation following optimal medical therapy (see Policy Guidelines).

The use of balloon ostial dilation for the treatment of chronic rhinosinusitis is considered **investigational** when the above criteria are not met as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

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The use of balloon ostial dilation for the treatment of recurrent acute rhinosinusitis is considered **investigational** as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

**Policy Guidelines**

Inflammation may be documented by all of the following:

- Nasal endoscopy showing purulent (not clear) mucus or edema in the middle meatus, anterior ethmoid, or sphenoethmoid region.

**AND**

- Abnormal CT scan of the paranasal sinuses.

According to the 2015 American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) guideline on adult sinusitis, abnormal findings on CT imaging may include moderate-to-severe mucosal thickening, opacification, or air-fluid levels. A subsequent consensus statement on balloon dilation of the sinuses published by the AAO-HNS in 2018 states: "The requirement of objective evidence of inflammation in addition to sinonasal symptoms suggestive of rhinosinusitis is consistent with AAO-HNSF diagnostic criteria for rhinosinusitis. However, evidence of inflammation or other findings on a CT scan was not deemed sufficient alone to make a patient a candidate for balloon dilation. The consensus that both symptoms and objective evidence of sinonasal disease are needed to deem a patient appropriate for a SOD [sinus ostial dilation] procedure is also reflected in many of the randomized clinical trials involving balloon dilation. The inclusion criteria for many of these trials require that the patient be deemed appropriate for conventional sinus surgery, which includes a trial of medical therapy and the presence of sinonasal symptoms in addition to objective evidence of sinus mucosal inflammation. On the surface, this statement may seem incompatible with the guidelines that mandate the presence of objective findings but do not specify which objective findings those are (i.e., polyps, purulence, or CT findings) for the diagnosis of CRS. However, the panel felt that the transition from diagnosis to management requires additional information. In that vein, a CT scan is necessary before proceeding with surgical management, and the findings of that CT scan would direct which sinuses were to be addressed. It was also agreed that an improved taxonomy for the classification of sinusitis would be helpful to improve the quality of clinical research."

**Balloon Ostial Dilation (BOD) used in combination with Functional Endoscopic Sinus Surgery (FESS)**

- BOD when used as a tool during functional endoscopic sinus surgery (FESS) in the same sinus cavity is considered to be an integral part of the FESS procedure.
- When BOD is used as an adjunct to FESS (defined as FESS on one sinus and BOD on another sinus in the same individual during the same operation) medical necessity criteria for BOD apply to the sinus being considered for BOD.

**Considerations for the use of BOD in children under age 18 years include the following:**

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- U.S. Food and Drug Administration (FDA) labeling for several 510(k) cleared devices includes use in children 17 years of age and under and is indicated to dilate sinus ostia and spaces associated with the maxillary sinus for diagnostic and therapeutic procedures.
- A 2014 AAO-HNS Clinical Consensus Statement on Pediatric Chronic Rhinosinusitis had near consensus on the safety of BOD in children but did not reach a consensus on efficacy.
- American Academy of Pediatrics Clinical Practice Guidelines only address the diagnosis and treatment of acute bacterial rhinosinusitis.

### ***Cross-References:***

**MP 1.140 Steroid-Eluting Sinus Stents and Implants**

**MP 1.157 Balloon Dilation of the Eustachian Tube**

### **PRODUCT VARIATIONS**

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

**FEP PPO** - Refer to FEP medical policy manual. The FEP medical policy manual can be found at: [fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies](http://fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies).

### **DESCRIPTION/BACKGROUND**

Rhinosinusitis can be classified according to the duration of symptoms. Acute rhinosinusitis lasts fewer than 4 weeks, while subacute sinusitis lasts between 4 and 12 weeks. Chronic rhinosinusitis (CRS) lasts more than 12 weeks. Recurrent acute rhinosinusitis (RARS) is defined as experiencing 4 or more episodes of acute rhinosinusitis per year and without persistent symptoms in between individual episodes. Rhinosinusitis affects 1 in 8 adults and accounts for 20% of antibiotic prescriptions. A longitudinal analysis of a medical claims database from 2003-2008 showed that 1 in 3,000 individuals had RARS, with 72% being female and an average age of 43.5 years. Individuals had an average of 5.6 healthcare visits and 9.4 prescriptions annually.

### **Chronic Rhinosinusitis**

CRS is a highly prevalent inflammatory disorder of the paranasal sinuses and the mucosa of the nasal passages that affects 3% to 7% of adults. In adults, CRS is characterized by symptoms related to nasal and sinus obstruction and inflammation, including mucopurulent nasal drainage, nasal congestion, facial pain or pressure, and anosmia or hyposmia, that persist for at least 12 weeks.

Three CRS subtypes exist and may have somewhat different treatment strategies: CRS without nasal polyposis; CRS with nasal polyposis; and allergic fungal sinusitis. The latter is a less common subtype thought to result from chronic allergic inflammation to colonizing nasal fungi. This evidence review focuses on the more common subtypes: CRS with and without nasal

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polyposis. Both subtypes present with similar symptoms. However, CRS with nasal polyposis is, by definition, associated with nasal polyps that are visible on rhinoscopy or nasal endoscopy. Further, CRS with nasal polyposis is more likely to be associated with asthma and aspirin intolerance; this triad is referred to as Samter syndrome or aspirin-exacerbated respiratory disease.

Chronic rhinosinusitis is associated with impaired quality of life for affected patients, and with high direct and indirect costs for medical treatments and lost productivity. Most often, the negative health effects of CRS are related to the unpleasant symptoms associated with CRS, including nasal congestion, nasal drainage, and facial pain or pressure. In rare cases, CRS can be associated with serious complications, including orbital cellulitis, osteomyelitis, or intracranial extension of infection.

While acute sinusitis is considered a more traditional infectious process, CRS is a chronic inflammatory disease of the upper airways, with multiple underlying causes. Risk factors for CRS with or without nasal polyps include anatomic variations and gastroesophageal reflux. There are conflicting reports about the association between allergy and CRS without nasal polyps, although weak evidence has suggested that allergy may be associated with CRS with nasal polyps. In addition, aspirin sensitivity may be associated with CRS with nasal polyps. The role of bacterial, viral, and fungal microorganisms in CRS has been actively investigated. There is some evidence that CRS is associated with a predominance of anaerobic bacteria. On the other hand, a study that used bacterial ribosomal RNA sequencing to evaluate the sinus microbiome in patients with and without CRS found a quantitative increase in bacterial and fungal RNA expression in patients with CRS, but no major differences in the types of microorganisms detected. Bacterial biofilms have been identified in cases of CRS.

### Recurrent Acute Rhinosinusitis

RARS is defined as having four or more episodes of acute bacterial rhinosinusitis per year, with no symptoms between episodes. Diagnosis is primarily based on medical history and physical examination, following the guidelines of the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS). Because other diseases can present with similar symptoms, it is important to consider various differential diagnoses. Nasal endoscopy is recommended for severe, one-sided, or persistent cases without septal deviation. Routine radiological imaging is generally not necessary for uncomplicated RARS, but noncontrast CT scans are crucial for chronic cases, suspected anatomical problems, or when planning surgeries like balloon ostial dilation (BOD) or functional endoscopic sinus surgery (FESS). The outlook for RARS is usually positive, with most patients responding well to treatments such as topical nasal sprays and oral antibiotics. It is rare for patients to need hospitalization, surgery, or intravenous antibiotics for complications. BOD has been proposed as a viable treatment option to provide symptom relief and an improved quality of life.

### Medical Therapy

Most cases of CRS and RARS are treated with medical therapy (e.g., antihistamines, steroids, nasal lavage, and antibiotics).

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Medical therapy for CRS, with or without polyps, is often multimodal, including nasal irrigation, topical and/or systemic corticosteroids, monoclonal antibodies, and/or antibiotic therapy. Guidelines from the AAO-HNS (2025) recommend the use of saline nasal irrigation, topical intranasal corticosteroids, or both, for symptom relief of CRS, on the basis of systematic reviews of randomized controlled trials (RCTs). There is a specific recommendation against the use of topical and systemic antifungal therapies. The guidelines recommend against routine use of antimicrobial therapy for CRS without exacerbation.

In 2019, the U.S. Food and Drug Administration (FDA) approved the first treatment for CRS with nasal polyps - dupilumab (Dupixent®). Results from clinical trials revealed that patients who received dupilumab "had statistically significant reductions in their nasal polyp size and nasal congestion compared to the placebo group" and also "reported an increased ability to smell and required less nasal polyp surgery and oral steroids." This was followed by the approval of omalizumab (Xolair®) in 2020 as add-on maintenance treatment for adults with nasal polyps with an inadequate response to nasal corticosteroids. In 2021, mepolizumab (Nucala®) was also approved as an add-on maintenance treatment in adults with CRS with nasal polyps. Tezepelumab was approved in 2025 as add-on maintenance treatment of adults and pediatric patients 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps.

The mainstay of treatment for RARS is medical management, which often involves a multifaceted therapeutic approach. Patients typically benefit from a range of treatments aimed at different aspects of RARS's complex pathophysiology. These may include topical intranasal therapies, antibiotics, decongestants, oral antihistamines, steroids, and leukotriene modifiers.

### Functional Endoscopic Sinus Surgery

The goals of surgery for CRS include removing polyps and debris that may be sources of inflammatory mediators and preventing the effective delivery of local medical therapies. In addition, to varying degrees, surgical techniques involve the creation of open sinus cavities, usually via dilation of the sinus ostia, to permit better drainage from the sinus cavities and more effective delivery of local therapies.

Techniques for FESS, in which an endoscope is used to access the sinus cavities and varying degrees of tissue are removed and the sinus ostia are opened, have evolved since the development of the nasal endoscope in the 1960s. FESS has largely replaced various open techniques for CRS (e.g., Caldwell-Luc procedure), although open procedures may have a role in complicated sinus pathologies (e.g., endonasal tumors). FESS encompasses a variety of degrees of sinus access and tissue removal and is described based on the sinuses accessed. This procedure can also be used to access the ethmoid sinuses, which may involve creation of drainage into the maxillary sinuses (maxillary antrostomy).

### Balloon Ostial Dilation

Balloon ostial dilatation can be used as an alternative or as an adjunct to FESS for those with CRS or RARS. The goal of this technique, when used as an alternative to FESS, is to improve sinus drainage using a less invasive approach. The procedure involves placing a guidewire in the sinus ostium, advancing a balloon over the guidewire, and then stretching the opening by inflating the balloon. The guidewire location is confirmed with fluoroscopy or with direct

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transillumination of the targeted sinus cavity. General anesthesia may be needed for this procedure to minimize patient movement. According to the manufacturer, the RELIEVA SPINPLUS® Balloon Sinuplasty System is intended to provide a means to access the sinus space and illuminate within and transilluminate across nasal and sinus structures; dilate the sinus ostia and spaces associated with the paranasal sinus cavities for diagnostic and therapeutic procedures; and irrigate from within a target sinus for therapeutic procedures and to facilitate diagnostic procedures.

This evidence review is limited to BOD when used as a standalone procedure. BOD may also be used in combination with FESS. When used as an adjunct to FESS, it is intended to facilitate and/or increase access to the sinuses. BOD may also be used on one sinus and FESS on another sinus in the same patient during the same operation.

### Regulatory Status

In 2008, the Relieva™ Sinus Balloon Catheter (Integra LifeSciences, formerly Acclarent Inc.) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA determined that this device was substantially equivalent to existing devices for use in dilating the sinus ostia and paranasal spaces in adults and maxillary sinus spaces in children. Subsequent devices developed by Acclarent have also been cleared by FDA through the 510(k) process (see Table 1 below).

In 2008, the FinESS™ Sinus Treatment (Entellus Medical, Maple Grove, MN) was cleared for marketing by FDA through the 510(k) process. The indication noted is to access and treat the maxillary ostia/ethmoid infundibulum in adults using a transantral approach (FDA product code: EOB). The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures. Two other balloon sinus ostial dilation devices, the ENTrigue® Sinus Dilation System (ENTrigue Surgical, acquired by more recently by Smith & Nephew), and the XprESS™ Multi-Sinus Dilation Tool, also received 510(k) clearance in 2012.

In 2013, a sinus dilation system (Medtronic Xomed, Jacksonville, FL), later named the NuVent™ EM Balloon Sinus Dilation System, was cleared for marketing by FDA through the 510(k) process for use in conjunction with a Medtronic computer-assisted surgery system when surgical navigation or image-guided surgery may be necessary to locate and move tissue, bone, or cartilaginous tissue surrounding the drainage pathways of the frontal, maxillary, or sphenoid sinuses.

Also in 2013, a sinus dilation system (Smith & Nephew), later named the Ventera™ Sinus Dilation System, was cleared for marketing through the 510(k) process to access and treat the frontal recesses, sphenoid sinus ostia, and maxillary ostia/ethmoid infundibula in adults using a transnasal approach. Ventera™ Sinus Dilation System does not require a guide wire or an illumination system as it is intended for use as a tool in combination with endoscopic sinus surgery.

Table 1 summarizes the currently FDA cleared balloon sinus dilation devices.

FDA product code: LRC.

### Table 1. Balloon Ostial Dilation Devices Cleared by the US Food and Drug Administration

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<b>Device</b>	<b>Manufacturer</b>	<b>510(k) No.</b>	<b>Date Cleared</b>	<b>Indication</b>
<b>Relieva Ultirra Sinus Balloon Catheter</b>	Acclarent, Inc.	K190525	05/03/2019	Sinus Ostia Dilation
<b>Sinusway Dilation System</b>	3NT Medical Ltd.	K181838	12/20/2018	Sinus Ostia Dilation
<b>MESIRE - Balloon Sinus Dilatation System</b>	Meril Life Sciences	K172737	12/12/2017	Sinus Ostia Dilation
<b>Relieva SpinPlus Nav Balloon Sinuplasty System</b>	Acclarent, Inc.	K171687	10/13/2017	Sinus Ostia Dilation
<b>Relieva UltirraNav Sinus Balloon Catheter</b>	Acclarent Inc.	K161698	10/24/2016	Sinus Ostia Dilation
<b>Vent-Os Sinus Dilation Family</b>	Sinusys Corp.	K160770	6/29/2016	Sinus Ostia Dilation
<b>Relieva Scout Multi-Sinus Dilation System</b>	Acclarent Inc.	K153341	2/12/2016	Sinus Ostia Dilation
<b>XprESS Multi-Sinus Dilation System</b>	Entellus Medical Inc.	K152434	11/20/2015	Sinus Ostia Dilation
<b>DSS Sinusplasty Balloon Catheter</b>	Intuit Medical Products LLC	K143738	8/27/2015	Sinus Ostia Dilation
<b>Relieva SpinPlus Balloon Sinuplasty System</b>	Acclarent Inc.	K143541	4/22/2015	Sinus Ostia Dilation
<b>XprESS Multi-Sinus Dilation Tool</b>	Entellus Medical Inc.	K142252	10/17/2014	Sinus Ostia Dilation

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<b>Relieva Scout Multi-Sinus Dilation System</b>	Acclarent Inc.	K140160	2/20/2014	Sinus Ostia Dilation
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**RATIONALE**

**Summary of Evidence**

For individuals with CRS who receive BOD as a stand-alone procedure, the evidence includes systematic reviews, randomized controlled trials (RCTs), and observational studies. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. A meta-analysis of 14 RCTs found BOD patients had lower postoperative Sino-Nasal Outcome Test (SNOT-20) scores, shorter operating time, and lower postoperative complications compared with functional endoscopic sinus surgery (FESS). However, there was no difference between groups in revision surgery or Lund-Mackay scores. A meta-analysis of three studies indicated a statistically significant yet not clinically significant preference for BOD over FESS in terms of patient-related quality of life. The REMODEL RCT confirmed that BOD was not inferior to FESS for treating chronic rhinosinusitis, with the effect's durability observed over 24 months. In a retrospective cohort study that used data from a large commercial insurance database to examine adverse events in individuals who underwent BOD (n=2851) or FESS (n=11,955), the overall complication rate was 5% with BOD and 7% with FESS. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with RARS who receive BOD as a stand-alone procedure, the evidence includes a systematic review and RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. A systematic review on RARS management identified two (of 10) studies focused on BOD as a treatment modality. Although an improvement in quality of life was observed across both studies, the small sample sizes, diverse outcome measures, and study heterogeneity prevented the authors from conducting a meta-analysis. In the REMODEL RCT, 32% of participants (N=29) with RARS were diagnosed. BOD was found to be non-inferior to FESS in terms of quality of life at both 6- and 12-months post-procedure. Another RCT, CABERNET, comparing BOD plus medical care to medical care alone in individuals with RARS (N=59), demonstrated significantly improved quality of life and fewer sinus infections after 6 months in the balloon dilation group. The current body of evidence is limited by small sample sizes, unblinded outcome assessment, lack of appropriate comparators, and heterogeneity in outcome measures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**DEFINITIONS**

NA

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### DISCLAIMER

*Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as permitted by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.*

### CODING INFORMATION

**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

#### Medically necessary when used to treat chronic rhinosinusitis:

Procedure Codes							
31295	31296	31297	31298	C1726			

ICD-10-CM Diagnosis Codes	Description
J32.0	Chronic maxillary sinusitis
J32.1	Chronic frontal sinusitis
J32.2	Chronic ethmoidal sinusitis
J32.3	Chronic sphenoidal sinusitis
J32.4	Chronic pansinusitis
J32.8	Other chronic sinusitis
J32.9	Chronic sinusitis, unspecified

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## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>BALLOON OSTIAL DILATION FOR THE TREATMENT OF CHRONIC RHINOSINUSITIS AND RECURRENT ACUTE RHINOSINUSITIS</b>
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### POLICY HISTORY

<b>MP 1.119</b>	<b>04/14/2020 Consensus Review.</b> Policy statement unchanged. Background and references updated. Coding reviewed.
	<b>07/17/2020 Minor Review.</b> Policy statement updated to include medically necessary indications for balloon ostial dilation. Policy guidelines added. Product variation, background, rationale, benefit variation, disclaimer,

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	references, and coding updated.
	<b>05/17/2021 Minor Review.</b> Policy Guidelines updated, added, “in the sinus (es) (to be) treated with BOD”. References reviewed and updated. Product variations updated.
	<b>03/31/2022 Consensus Review.</b> No change to policy statement. Policy Guidelines revised (removed table). Cross Referenced policies and FEP statement modified. Background and References updated.
	<b>03/24/2023 Minor Review.</b> BOD for recurrent acute rhinosinusitis is now MN with specific criteria. Cough added as a symptom for the pediatric population. Antibiotics and decongestants are required “when indicated”. Corticosteroids and saline nasal irrigation use changed from 8 weeks to 4 weeks. Removed requirement re: trial of discontinuation of meds that can cause nasal congestion. Diagnosis of CRS must include one or more of the objective findings listed. CT is required prior to surgery. Policy guidelines, background, rationale, and references updated. Removed procedure codes 31256, 31276, 31287. Added dx codes for recurrent acute rhinosinusitis.
	<b>02/13/2024 Consensus Review.</b> References updated. Updated coding by removing unlisted code since balloon dilation has specific codes.
	<b>02/13/2025 Minor Review.</b> Updated statement criteria for CRS. Recurrent acute rhinosinusitis is now INV. Updated policy guidelines, cross-references, background, rationale, ICD-10 table and references.
	<b>06/10/2025 Administrative Update.</b> Removing the Benefit Variations and updating the Disclaimer.
	<b>02/17/2026 Consensus Review.</b> Updated cross-references, background, rationale, and references. No changes to coding.

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