NO. 91596

BALLOON SINUS OSTIAL DILATION FOR CHRONIC SINUSITIS AND EUSTACHIAN TUBE DILATION

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Policy scope: This policy addresses the medical necessity and coverage criteria for balloon sinus ostial dilation for the treatment of chronic rhinosinusitis and recurrent acute rhinosinusitis and for Eustachian Tube Dysfunction.

Related policies:

- None

I. MEDICAL NECESSITY CRITERIA

A. Balloon Sinus Ostial Dilation

Inclusions:

1. Chronic Rhinosinusitis (CRS)

The use of balloon sinus ostial dilation (e.g., Balloon Sinuplasty™), for the treatment of chronic rhinosinusitis (CRS) is considered medically necessary when **all** of the following criteria are met:

a. Documentation of chronic rhinosinusitis for greater than three months, defined as the presence of two or more sinonasal symptoms, at least one of which must be nasal obstruction/congestion or nasal drainage; **AND**

b. Documented failure of appropriate medical therapy of adequate duration, demonstrated by persistent symptoms despite medical management; **AND**

c. Objective radiological evidence of sinonasal disease in the sinus (es) to be dilated, demonstrated by at least **ONE** of the following:
    i. Air fluid levels; **or**
    ii. Mucosal thickening > 2 mm; **or**
    iii. Partial or complete opacification; **or**
    iv. Obstructive inflammatory tissue consistent with nasal polyposis (when present, nasal endoscopy may be used to document extent).

2. Recurrent Acute Rhinosinusitis (RARS)

Balloon sinus ostial dilation (e.g., Balloon Sinuplasty™), for the treatment of recurrent acute rhinosinusitis (RARS) is considered medically necessary when **all** of the following criteria are met:

a. Documentation of four or more episodes of acute bacterial rhinosinusitis within 12 continuous months, with complete resolution of symptoms between episodes; **AND**

b. Documentation of failure of appropriate medical therapy for each episode including antibiotics when bacterial infection is suspected and adjunctive therapies such as intranasal corticosteroid spray, and/or saline nasal irrigation); **AND**

c. Sinonasal symptoms (e.g., facial pressure/pain, purulent drainage) are present on the same side as CT scan findings of rhinosinusitis; **AND**

d. Objective radiological evidence of sinonasal disease, demonstrated by at least **ONE** of the following:
    i. Air fluid levels; **or**
    ii. Mucosal thickening > 2 mm; **or**
    iii. Partial or complete opacification; **or**
    iv. Obstructive inflammatory tissue consistent with nasal polyposis

Exclusions:

1. The following are not considered medically necessary:

a. Patients without radiographic or endoscopic evidence of sinonasal disease consistent with CRS or RARS.

b. Use of balloon dilation for non-sinonasal indications such as headache, facial pain, or nasal symptoms without a diagnosis of CRS or RARS.

Limitations:

1. Balloon sinus ostial dilation when performed as an adjunct to functional endoscopic sinus surgery (FESS) is considered integral to the primary FESS procedure and is not separately reimbursable.

Not Medically Necessary- Considered Experimental / Investigational:

1. The following are considered experimental, investigational, or unproven due to insufficient evidence of clinical benefit:

a. **Sinus Ostial Maintenance Devices**
   i. Devices used to maintain sinus ostial patency following balloon dilation or endoscopic sinus surgery, including but not limited to:
      a) Propel™ sinus implant
      b) Relieva Stratus™ MicroFlow spacer
      c) Sinu-Foam™ spacer

b. **Indications Outside Policy Criteria**
   i. Balloon sinus ostial dilation for indications not meeting the inclusion criteria above.

B. Eustachian Tube Balloon Dilation

Inclusions:

1. Chronic Obstructive Eustachian Tube Dysfunction in Adults

Unilateral or bilateral Eustachian tube balloon dilation (ETBD) is considered medically necessary once per lifetime for the treatment of chronic obstructive Eustachian tube dysfunction for adults (18 and older) when ALL of the following criteria are met:

a. Any of the following symptoms continuously for greater than or equal to at least 3 months:
   i. aural fullness (clogged ear sensation)
   ii. aural pressure or otalgia
   iii. hearing loss
   iv. autophony

Note: standardized patient reported questionnaire (ETDQ-7) recommended

b. History of obstructive ETD or intolerance to barometric changes greater than six months

c. Tympanic membrane abnormality (i.e., retracted membrane, effusion) on exam

d. Complete nasal endoscopy assessing the Eustachian tube (ET) lumen confirming transnasal access to the nasopharynx and eliminating extrinsic causes of Eustachian tube dysfunction (ETD)

e. Failure, intolerance or contraindication to appropriate medical management of co-occurring conditions (rhinosinusitis, allergic rhinitis, laryngopharyngeal reflux)

f. Tympanometry of intact tympanic membrane showing either:
    i. Type A tympanogram (only provided that symptom relief occurred with prior myringotomy and tympanostomy tubes), **OR**
    ii. Type B or Type C tympanogram

g. If history of prior tympanostomy tube placement, relief from classic Eustachian tube obstructive symptoms must be demonstrated while tubes were patent

2. Chronic Obstructive Eustachian Tube Dysfunction in Pediatrics

Balloon dilation of the Eustachian tube (BDET) is considered medically necessary for select **pediatric members (ages 8 to 17)** when **ALL** of the following criteria are met:

a. The member has obstructive Eustachian tube dysfunction; **AND**

b. The member has chronic otitis media refractory to standard surgical interventions (e.g., tympanostomy tube placement **and** adenoidectomy).

Exclusions:

1. The following patients **(Adults and Pediatrics)** should **not** be considered for balloon dilatation of the Eustachian Tube:

a. Patulous ETD (demonstrated by autophony of voice, pulsatile tinnitus, and/or aural fullness, visible respiratory variation of tympanic membrane (TM))

b. Extrinsic or structural causes of Eustachian tube dysfunction, including but not limited to:
    i. Neoplasm
    ii. Nasopharyngeal mass or other sources of extrinsic compression

iii. Untreated enlarged adenoids (particularly in pediatric patients)
iv. Congenital craniofacial syndromes (e.g., Cleft palate)
v. Chronic degenerative neuromuscular conditions resulting in adynamic eustachian tube
vi. Active *uncontrolled* systemic mucosal or autoimmune inflammatory conditions affecting nasal mucosa

c. Symptoms attributable to non–Eustachian tube etiologies, including:
   i. Temporomandibular joint disorders
   ii. Superior semicircular canal dehiscence
   iii. Endolymphatic hydrops / Ménière disease

d. Episodic or baro-challenge–only symptoms (e.g., symptoms occurring only with flying, driving, or altitude changes)

e. Prior Eustachian tube balloon dilation procedure

Limitations:

1. Patients undergoing Balloon Dilation of the Eustachian Tube (BDET) **concurrent with sinus ostial dilation or myringotomy** should meet the same diagnostic criteria as those undergoing BDET alone.

2. **Repeat** ETBD is considered not medically necessary due to insufficient evidence.

Not Medically Necessary as Considered Experimental / Investigational:

1. The following are considered **experimental, investigational, or unproven** due to insufficient evidence of clinical benefit:

   a. Balloon Eustachian tube balloon dilation (ETBD) for indications not meeting the inclusion criteria above.

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
None Identified	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None Identified
First Coast Service Options, Inc.	None Identified
National Government Services, Inc.	None Identified
Noridian Healthcare Solutions	None Identified
Novitas Solutions, Inc.	None Identified
Palmetto GBA	None Identified
WPS Insurance Corporation	None Identified

III. BACKGROUND

Chronic rhinosinusitis (CRS) is an inflammatory condition of the paranasal sinuses characterized by persistent sinonasal symptoms and objective evidence of mucosal disease lasting at least 12 weeks. CRS is multifactorial in etiology and may be associated with chronic allergic inflammation, anatomic obstruction (e.g., deviated nasal septum, turbinate hypertrophy), impaired mucociliary clearance, or odontogenic sources such as dental infections extending into the maxillary sinuses. The disease process is heterogeneous, with variable symptom severity, anatomic involvement, and response to medical therapy (Shin et al., 2025).

Recurrent acute rhinosinusitis (RARS) is distinguished from CRS by discrete episodes of acute bacterial rhinosinusitis, typically defined as four or more episodes within a 12-month period, with complete resolution of symptoms between episodes (American Rhinologic Society [ARS], 2023). Although patients with RARS do not demonstrate persistent mucosal inflammation between episodes, recurrent infections may be related to underlying anatomic obstruction, impaired sinus drainage, or mucosal dysfunction, similar to mechanisms observed in CRS (ARS, 2023).

Initial management of CRS and RARS is generally medical and may include intranasal corticosteroids, saline irrigation, treatment of contributing conditions such as allergic rhinitis, and antibiotics when bacterial infection is suspected (Shin et al., 2025; ARS, 2023). However, medical therapy does not uniformly result in symptom resolution, and some patients experience persistent disease or recurrent infections despite appropriate conservative management.

The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) Clinical Practice Guideline for the Surgical Management of Chronic Rhinosinusitis (2025) recognizes that CRS is a heterogeneous condition and that patient response to medical therapy varies widely. Accordingly, the guideline advises that clinicians should not require or endorse a predefined, uniform medication regimen or fixed duration of medical

therapy—including antibiotics, systemic or topical corticosteroids, or antihistamines—as a prerequisite to sinus surgery in adults with CRS (Shin et al., 2025).

Evidence from randomized controlled trials and meta-analyses demonstrates variable quality and inconsistent outcomes across medical therapies used in CRS, with no single regimen shown to be universally effective. As a result, rigid requirements for “maximal” or standardized medical therapy prior to surgical intervention are not supported by the available evidence (Shin et al., 2025).

The guideline emphasizes that decisions regarding medical management and timing of surgery should be individualized and patient-centered, incorporating the patient’s clinical history, symptom severity, physical examination findings, and objective evidence of disease. Objective data may include imaging studies, laboratory findings, and prior pathology results, as clinically appropriate (Shin et al., 2025). This approach supports the use of clinical judgment and shared decision-making, rather than mandatory medication thresholds, to determine when surgical management of CRS is medically necessary and appropriate (Shin et al., 2025).

Balloon sinus ostial dilation (also referred to as Balloon Sinuplasty™) has been developed as a minimally invasive technique to improve sinus drainage by mechanically dilating obstructed sinus ostia. The procedure may be performed as a standalone intervention or as an adjunct to functional endoscopic sinus surgery (FESS) (AAO-HNS, 2021; ARS, 2023). Balloon dilation systems involve placement of a catheter-based balloon into the targeted sinus ostium—typically via a transnasal endoscopic approach—followed by balloon inflation to remodel the ostial opening while preserving mucosal tissue (AAO-HNS, 2021).

Consistent with evidence-based society guidelines, balloon sinus ostial dilation is recognized as an appropriate therapeutic option for carefully selected patients with CRS or RARS who have objective evidence of sinonasal obstruction and have failed appropriate medical management. The AAO-HNS and the American Rhinologic Society support the use of sinus ostial dilation, including balloon-based techniques, as a treatment option for adults with CRS or RARS when performed in accordance with established diagnostic criteria and patient selection standards (AAO-HNS, 2021; ARS, 2023). Society guidance emphasizes that the procedure may be performed as a standalone intervention or as an adjunct to endoscopic sinus surgery, depending on disease severity and anatomic involvement (AAO-HNS, 2021; ARS, 2023).

Drug Eluting Devices

Drug-eluting sinus implants provide localized delivery of corticosteroids to the sinonasal mucosa and are recognized by the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) as an effective option for reducing mucosal inflammation and promoting postoperative healing following endoscopic sinus surgery (ESS) (AAO-HNS, 2023). A systematic review and meta-analysis of randomized controlled trials

demonstrated that steroid-eluting middle meatal implants placed after ESS were associated with significant short-term improvements, including reduced adhesion (synechiae) formation, decreased mucosal inflammation, lower rates of recurrent nasal polyposis, and reduced need for systemic corticosteroids or early revision surgery. However, several benefits were not sustained at longer follow-up intervals, and long-term clinical outcomes remain uncertain (Zamaili et al., 2025).

Additional evidence from a multicenter, randomized, controlled, single-blinded trial demonstrated that bioabsorbable steroid-eluting sinus stents placed following ESS resulted in improved early postoperative outcomes compared with absorbable nasal packing (Nasopore). In this contralateral-control study of 181 patients, steroid-eluting stents were associated with a statistically significant reduction in postoperative surgical intervention at 30 days and lower rates of postoperative polyp formation through 90 days. Severe adhesions were reduced at 90 days, with no significant differences observed in middle turbinate lateralization and no device-related adverse events reported. Study limitations included lack of sustained blinding and the absence of long-term outcomes, including revision ESS rates (Huang et al., 2022).

Eustachian tube dysfunction (ETD) is a disorder characterized by impaired pressure regulation and ventilation of the middle ear due to abnormal Eustachian tube function. ETD exists along a spectrum ranging from obstructive ETD, in which the Eustachian tube fails to open adequately, to patulous ETD, in which the tube fails to close properly, complicating diagnosis and management. Management is directed at the underlying etiology and typically begins with medical therapy, including nasal or systemic medications, as well as pressure-equalization strategies. Eustachian tube balloon dilation (ETBD) is a procedural treatment option for obstructive ETD and involves dilation of the cartilaginous portion of the Eustachian tube using an inflatable balloon catheter to improve Eustachian tube function.

In 2019, the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) published a Clinical Consensus Statement defining Eustachian tube balloon dilation (ETBD) as the temporary insertion and inflation of a balloon catheter within the cartilaginous portion of the Eustachian tube to alleviate obstructive Eustachian tube dysfunction (ETD) (Tucci et al., 2019). Based on a systematic review of the literature and expert consensus, the AAO-HNS emphasizes that appropriate patient selection for ETBD requires a comprehensive diagnostic evaluation, including detailed history and physical examination with otoscopy, objective testing such as tympanometry and comprehensive audiometry, and nasal endoscopy to exclude extrinsic causes of ETD (Tucci et al., 2019).

The consensus also notes that patient-reported symptom measures, including the seven-item Eustachian Tube Dysfunction Questionnaire (ETDQ-7), are useful for assessing baseline symptom severity and treatment response but are insufficient as standalone diagnostic tools for establishing a diagnosis of obstructive ETD (Tucci et al.,

2019). ETBD is contraindicated in patients with patulous ETD, and the benefit of repeat ETBD following a prior ineffective procedure has not been determined. The AAO-HNS recognizes ETBD as an alternative to tympanostomy tube placement for appropriately selected patients with obstructive ETD (Tucci et al., 2019).

The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) recognizes ETBD as an appropriate therapeutic option for select pediatric patients with obstructive ETD associated with chronic otitis media that is refractory to standard surgical interventions, including tympanostomy tube placement and adenoidectomy. Available evidence indicates that ETBD in appropriately selected pediatric patients is safe and is associated with improvements in hearing outcomes, tympanometric findings, and disease-specific quality of life, with a reduced need for additional surgical interventions. Patient candidacy should be determined by a qualified otolaryngologist, and devices used for ETBD should be approved by the U.S. Food and Drug Administration (FDA) for the indicated use (AAO-HNS, 2025).

Tympanometry is an objective diagnostic test that assesses middle ear function by measuring changes in acoustic impedance in response to variations in air pressure within the ear canal. The test identifies the point of maximum tympanic membrane compliance, which reflects middle ear pressure status. Tympanometric results are categorized into standardized patterns, including Type A (normal middle ear pressure), Type B (reduced or absent membrane mobility, commonly associated with middle ear effusion or tympanic membrane perforation), Type C (negative middle ear pressure suggestive of Eustachian tube dysfunction), Type As (reduced compliance due to increased stiffness, such as myringosclerosis or otosclerosis), and Type Ad (excessive compliance associated with ossicular chain discontinuity).

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
American Academy of Otolaryngology – Head and Neck Surgery Foundation (AAO-HNSF)	Clinical Consensus Statement: Balloon Dilation of the Sinuses (2018) Position Statement: Dilation of sinuses, any method (e.g., balloon, etc.) - American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) (2021) Position Statement: Drug-Eluting Sinus Implants - American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) (2023) Eustachian Tube Balloon Dilation in the Pediatric Population - American

	Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) (2025)
International Forum of Allergy and Rhinology (IFAR)	International consensus statement on allergy and rhinology: rhinosinusitis 2021
The American Rhinologic Society (ARS)	Ostial Balloon Dilation Position Statement (2023) Drug Eluting Implants (2023)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date
Balloon Sinus Ostial Dilation Systems		
Relieva SpinPlus Balloon Sinuplasty System (Acclarent Inc.)	K143541	04/22/2015
XprESS Multi-sinus dilation system (Entellus/Stryker)	K152434	11/20/2015
Relieva™ Ultirra™ Sinus Balloon Catheter (Acclarent)	K190525	03/04/2019
Relieva Sinus Balloon Catheter (Acclarent Inc.)	K061903	08/18/2006
Relieva Seeker Balloon Sinuplasty System (Acclarent Inc.)	K120280	11/5/2012
Next Generation Balloon (NGB) System (Acclarent)	K201115	08/27/2020
NuVent™ EM Balloon Sinus Dilation System (Medtronic)	K152121	2018–2020 era
Drug-Eluting Stents		
PROPEL CONTOUR SINUS IMPLANT	P100044	08/11/2011
Eustachian Tube Balloon Dilation Systems		

Acclarent AERA® Eustachian Tube Balloon Dilation System (Johnson & Johnson MedTech)	K171761 K230742 **(Pediatric (8-17) indication** K253612	01/16/2018 11/13/2023 02/16/2026
NuVent™ Eustachian Tube Dilation Balloon (Medtronic)	K210841	08/16/2021
VenSure™ Balloon Dilation System (Sinus Indications) (Fiagon GmbH)	K230065	05/26/2023
XprESS ENT Dilation System (Entellus/Stryker)	K163509	04/5/2017
Audion Et Dilation System (Entellus Medical, Inc.)	K220027	4/12/2022

VI. CODING

ICD-10 Codes that may support medical necessity

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

CPT/HCPCS Codes

31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (e.g., balloon dilation), transnasal or via canine fossa
31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (e.g., balloon dilation)
31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (e.g., balloon dilation)
31298	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (e.g., balloon dilation)
69705	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral
69706	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral
C2625	Stent, noncoronary, temporary, with delivery system
J7402	Mometasone furoate sinus implant, (Sinuva), 10 mcg

Not Medically Necessary- Considered Experimental / Investigational:

S1091	Stent, noncoronary, temporary, with delivery system (Propel)

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

General Guidelines and Publications

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Balloon Sinus Ostial Dilation

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Eustachian Tube Dilation

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SUMMARY OF CHANGES

Deletions:

- Removed tobacco use as an exclusion for Eustachian tube balloon dilation (ETBD)

Additions:

- Added medical necessity criteria for recurrent acute rhinosinusitis
- Added medically necessity criteria for chronic obstructive Eustachian tube dysfunction in pediatrics (ages 8-17).

Changes:

- Removed age criteria of 18 and up for eustachian tube dysfunction. New section was added with medical necessity criteria for pediatric members ages 8-17.
- Removed the strict ≥3-month predefined medical therapy regimen requirement for chronic rhinosinusitis, allowing individualized, patient-centered medical management prior to surgery
- Symptom duration threshold for ETBD (6 → 3 months)
- Moved section “B” that speaks to billing criteria for balloon sinus ostial dilation to new "limitations" section of policy

Clarifications:

- Made editorial and grammatical updates to improve clarity.

Past committee review dates:12/2011, 12/2012, 2/2013, 2/2014, 2/2015, 2/2016, 2/2017, 2/2018, 2/2019, 2/2020, 2/2021, 2/2022, 2/2023, 2/2024, 5/2024, 5/2025, 05/2026