Effective April 1, 2021, refer to Medicare Benefit Policy Manual Chapter 15, Section 50 for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Implantable Sinus Stents for Postoperative Use Following Endoscopic Sinus Surgery and for Recurrent Sinus Disease

Policy #: 501
Latest Review Date: March 2017
Category: Surgery
ARCHIVED EFFECTIVE 4/1/2021

Background:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage*

Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).

Description of Procedure or Service:

Sinus stents are devices that are used postoperatively following endoscopic sinus surgery (ESS). These devices are used to maintain patency of the sinus openings in the postoperative period, and/or to serve as a local drug delivery vehicle. Reducing postoperative inflammation and maintaining patency of the sinuses may be important in achieving optimal sinus drainage and may impact recovery from surgery.

Endoscopic sinus surgery (ESS) is typically performed in patients with chronic rhinosinusitis unresponsive to conservative treatment. The surgery is associated with improvements in symptoms in up to 90% of more appropriately selected patients. However, there are no high-quality RCTS comparing functional ESS to continued medical management or alternative treatment approaches. Because of the high success rates and minimally invasive approach, these procedures have rapidly increased in frequency, with an estimated 250,000 procedures performed annually in the U.S. They can be done either in the physician's office under local anesthesia or in the hospital setting under general anesthesia.

ESS involves the removal of small pieces of bone, polyps, and debridement of tissue within the sinus cavities. There are a number of variations on the specific approach, depending on the disorders that are being treated and the preferences of the treating surgeon. For all procedures, there is a substantial amount of postoperative inflammation and swelling, and postoperative care is therefore a crucial component of ESS.

There are a number of postoperative treatment regimens, and the optimal regimen is not certain. Options include saline irrigation, nasal packs, topical steroids, systemic steroids, topical decongestants, oral antibiotics, and/or sinus cavity debridement. There have been a number of randomized controlled trials (RCTs) that have evaluated various treatment options, but all different strategies have not been rigorously evaluated. A systematic review evaluated the evidence for these therapies. The authors of this review concluded that the evidence was not strong for any of these treatments but that some clinical trial evidence supported improvements in outcomes. The strongest evidence supported use of nasal saline irrigation, topical nasal steroid spray, and sinus cavity debridement.

Some form of sinus packing is generally performed postoperatively. Simple dressings moistened with saline can be inserted manually following surgery. Foam dressings are polysaccharide substances that form a gel when hydrated and can be used as nasal packs for a variety of indications. Middle meatal spacers are splint-like devices that prop open the sinus cavities post-ESS, but are not designed for drug delivery. There is some RCT evidence that middle meatal spacers may reduce the formation of synechiae following ESS, although the available studies have significant heterogeneity in this outcome.

Implantable sinus stents are another option for postoperative management following ESS. These implants are intended to stabilize the sinus openings and the turbinates, reduce edema, and/or

prevent obstruction by adhesions. They also have the capability of being infused with medication that can be delivered topically over an extended period of time, and this local delivery of medications may be superior to topical application in the postoperative setting.

Sinus stents are defined as implantable devices that are specifically designed to improve patency and/or deliver local medication. These devices are inserted under endoscopic guidance and are distinguished from sinus packing and variations on packing devices that are routinely employed post sinus surgery.

Foam dressings, such as SinuFoam™, are used as nasal packs for a variety of conditions, including nosebleeds, and have also been used post-ESS. These are considered different types of nasal packing.

Middle meatal spacers are related but separate devices that are intended to maintain sinus patency post-ESS. They are splint-like devices that are inserted directly rather than under endoscopic guidance, and they do not have the capability of delivering local medication.

Policy:

For dates of service on or after March 24, 2020:

Blue Advantage will treat the use of **implantable sinus stents/spacers** as a **non-covered benefit** and as **investigational** for the following, including, but not limited to:

- Postoperative treatment following endoscopic sinus surgery;
- For treatment of recurrent sinonasal polyposis.

Effective for dates of service on or after February 26, 2018, to March 23, 2020, refer to LCD L34555

Effective for dates of service prior to February 26, 2018:

Blue Advantage will treat the use of **implantable sinus stents/spacers** as a **non-covered benefit** and as **investigational** for the following, including, but not limited to:

- Postoperative treatment following endoscopic sinus surgery;
- For treatment of recurrent sinonasal polyposis.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent literature search was performed through January 13, 2017. The following is a summary of the key findings to date.

Randomized controlled trials (RCTs) are important in the evaluation of sinus implants as an adjunct to endoscopic sinus surgery to adequately compare implantable stents to alternative treatment regimens and to minimize the effects of confounders on outcomes. Case series and trials without control groups offer little in the way of relevant evidence, as improvement in symptoms is expected after endoscopic sinus surgery (ESS) and because there are multiple clinical and treatment variables which may confound outcomes.

The most relevant comparison for sinus stents is unclear because there is not a standardized optimal postoperative treatment regimen. Ideally, the "standard care" comparison group should include some form of packing, intranasal steroids, and irrigation. An important consideration in evaluating controlled trials is that the control arm may not be treated with optimal intensity, thereby leading to a bias in favor of the device. For example, a study design that compares a steroid-eluting stent with a non-steroid-eluting stent will primarily evaluate the efficacy of steroids when delivered by the device, but will not evaluate the efficacy of a stent itself. If the control group does not receive topical or oral steroids postoperatively, then this might constitute undertreatment in the control group and result in a bias favoring the treatment group. Another concern is for the comparison of efficacy of a drug with the efficacy of a drug delivery system. For example, if a steroid-eluting spacer is compared to a control of saline irrigation alone, it will be difficult to separate the efficacy of the drug itself (steroids) from the drug delivery system (stent).

The literature consists of a few, small randomized trials, single-arm case series, and systematic reviews of these studies.

Steroid-Eluting Stents as an Adjunct to Endoscopic Sinus Surgery

Systematic Reviews

A 2015 Cochrane review addressed steroid-eluting sinus stents for improving chronic rhinosinusitis symptoms in individuals undergoing ESS. Study eligibility criteria were RCTs that studied the effects of steroid-eluting sinus stents compared with non-steroid-eluting sinus stents, nasal packing, or no treatment in adults with chronic rhinosinusitis who underwent ESS. After an initial search, 21 RCTs were identified, including the RCTs reported by Murr et al (2011) and Marple et al (2012) described above. None of the studies met the authors' inclusion criteria. The authors conclude that there is no evidence from high quality RCTs to demonstrate the benefits of steroid-eluting stents.

A systematic review of early postoperative care following ESS was published in 2011. This review evaluated a number of different postoperative regimens, including stents. The review included one RCT by Cote et al and two nonrandomized studies. Some of the devices included in these studies are considered middle meatal spacers and are outside the scope of this evidence review. The overall level of evidence was judged as B (RCT with limitations). The authors concluded that topical steroids delivered by the "nonstandard" route required further study and that the results of current studies could not be extrapolated to larger populations. Based on this

evidence, they did not recommend use of stents but considered them an "option" for postoperative care.

Han et al performed a meta-analysis of the two published RCTs of the Propel™ implant, both of which compared a steroid-eluting stent with a non-steroid-eluting stent. The results of the two RCTs were combined at the patient level, with reanalysis of the endoscopy videos by a panel of three independent ear, nose, and throat experts. The combined results were that the steroid-eluting device reduced postoperative interventions by 35% ($p=0.0008$), reduced lysis of adhesions by 51% ($p=0.0016$), and reduced the need for oral steroids by 46% ($p<0.0001$).

Randomized Controlled Trials

As noted, there are two small RCTs of the Propel™ sinus implant. Both trials have similar designs and both are sponsored by the manufacturer (Intersect ENT™, Palo Alto, CA.). Both compare an implant that is steroid-eluting versus an identical implant that is not steroid-eluting. Thus these trials test the value of drug delivery via a stent, but do not test the value of a stent itself versus treatment without a stent.

The first RCT of this implant was published in 2011 by Murr et al. A total of 38 patients with refractory chronic rhinosinusitis were included in the efficacy evaluation, and an additional five patients were enrolled for a safety evaluation. An intra-patient control design was used, meaning that each patient received a drug-eluting stent on one side and a non-drug-eluting stent on the other via random assignment. Patients were not permitted to use topical or oral steroids for 30 days following the procedure. A 14-day course of antibiotics was given to all patients. The primary end point was the degree of inflammation recorded on follow-up endoscopy at day 21 postprocedure, as scored by a 100 mm visual analogue scale (VAS). There were also semiquantitative grading performed for polypoid changes, middle turbinate position, and adhesions/synechiae. The clinicians recording the outcomes were the same physicians who were treating the patients**.** One patient withdrew prior to study completion.

The difference in inflammation scores at 21 days was significant in favor of the steroid-eluting group. The estimated difference in scores from graphical representation was approximately 18 units on the 0 to 100 VAS scale. The percent of patients having polypoid changes was 18.4% in the steroid-eluting group versus 36.8% in the non-steroid-eluting group ($p=0.039$). Adhesions were also significantly less common in the steroid-eluting group (5.3% vs. 21.1%, $p=0.03$). There were no significant differences in the appearance or position of the middle turbinate.

In 2012, Marple et al published results of the Advance II trial, an RCT of the Propel™ sinus implant for 105 patients with chronic rhinosinusitis refractory to medical management. This trial also used an intra-patient control design with each patient receiving a drug-eluting stent on one side and a non-drug-eluting stent on the other via random assignment. Patients were not permitted to use topical or oral steroids for 30 days following the procedure. A 14-day course of antibiotics was given to all patients. The primary efficacy outcome was reduction in the need for postoperative interventions at day 30 following the procedure. A panel of three independent experts, who were blinded to treatment assignment and clinical information, viewed the endoscopy results and determined whether an intervention was indicated. The primary safety end point was the absence of clinically significant increased ocular pressure through day 90.

There were three patients lost to follow-up (2.9%), and nine patients (8.6%) could not be evaluated because the video of the endoscopy could not be graded. Two patients had the device removed within 30 days of placement. Of the remaining patients, the need for postoperative intervention by expert judgment was found in 33.3% of patients in the steroid-eluting arm versus 46.9% in the non-steroid-eluting arm (p=0.028). According to the judgments of the clinical investigators who were treating the patients, intervention was required in 21.9% of the steroid-eluting group and 31.4% of the non-steroid-eluting group (p=0.068). The reduction in interventions was primarily driven by a 52% reduction in lysis of adhesions (p=0.005). The primary safety hypothesis was met, as there were no cases of clinically significant increases in ocular pressure recorded over the 90-day period following the procedure.

Nonrandomized Comparative Studies

The largest nonrandomized study identified was reported by Xu et al in 2015, which evaluated post-ESS synechiae formation among 146 patients (252 nasal cavities) treated with a steroid-eluting absorbable spacer and 128 patients (233 nasal cavities) treated with a nonabsorbable spacer. Eligible patients included those who underwent ESS (at minimum, maxillary antrostomy and anterior ethmoidectomy) for chronic rhinosinusitis with or without nasal polyps and were treated with a sinus spacer. Synechiae related outcomes were unavailable for 10 subjects in the absorbable spacer group (6.8%) and nine subjects in the nonabsorbable spacer group (7.0%) due to lack of 1-month follow up. Rates of synechiae formation at 1-month postoperatively did not differ significantly between groups (5 [2.0%] nasal cavities in the absorbable stent group vs 13 [5.6%] nasal cavities in the nonabsorbable spacer group).

Noncomparative Studies

In 2014, Matheny et al reported results from a single-arm case series evaluating the use of office-based placement of a mometasone-eluting absorbable stent (PROPEL device) within seven days of ESS including bilateral ethmoidectomy. Eligible patients had chronic rhinosinusitis with or without nasal polyps and were treated by one of three surgeons. The surgical procedure was ESS with complete ethmoidectomy, followed by packing with a chitosan-polyethylene glycol absorbable dressing. At outpatient follow-up scheduled five to seven days post-surgery, patients underwent debridement of the ethmoid cavity with placement of the steroid-eluting stent. Twenty patients who underwent 40 stent placements were included. Complications included acute sinusitis in two patients between two and four weeks post-surgery. Sinuses were evaluated based on video endoscopy by an independent reviewer using a 100-mm VAS and the standardized case report form described by Murr et al. Ethmoid sinus inflammation was reduced from 25.6 at baseline to 18.9 at week for (p=0.034). The mean total SNOT-20 score was reduced (improved) from 42.8 at baseline to 18.4 at week two and 8.9 at week four. The procedure was generally well-tolerated.

The ADVANCE study was a prospective, multicenter single-arm trial of placement of a mometasone-eluting absorbable stent in 50 patients who were scheduled to undergo ESS. As reported by Forwith et al (2011), the end points evaluated on follow-up endoscopies were the degree of inflammation scored on a 100 mm visual analog scale (VAS) and semiquantitative grading for polypoid changes, middle turbinate position, and adhesions. By day seven postprocedure, the inflammation scores were in the “minimal” range and remained there for the rest of the time points. At one month, polypoid lesions were present in 10% of patients,

adhesions in 1.1%, and middle turbinate lateralization in 4.4%. Scores on the Sino-Nasal Outcome Test-22 and the Rhinosinusitis Disability Index improved significantly in the first month post procedure.

A 2001 case series was published of 23 patients with refractory rhinosinusitis who underwent ESS and were treated postoperatively with the Relieva Stratus Microflow Spacer Device infused with triamcinolone. Over a period of six months, there were significant improvements on multiple sinus-related outcome measures such as the Sino-Nasal Outcome Test-20 and the Lund-McKay CT (computed tomography) scan scores. There were no significant intraoperative or postoperative complications reported.

Section Summary: Steroid-Eluting Stents as an Adjunct to Endoscopic Sinus Surgery
The most direct evidence relating to the use of steroid-eluting nasal stents as an adjunct to ESS comes from 2 RCTs comparing steroid-eluting stents with a non-steroid-eluting stent. One study used blinded assessors to evaluate post-implantation sinus changes, an important strength, but the trials have other potentials for bias. In addition, to most accurately evaluate the benefit from the Propel device, ensuring that the comparison group is not undertreated (i.e., receives some form of packing, intranasal steroids, and irrigation) is important.

Steroid-Eluting Stents for Recurrent Polyposis
A relatively small body of literature has addressed outcomes after placement of steroid-eluting absorbable sinus stents in the office setting as a planned procedure post-ESS or due to persistent/recurrent nasal polyposis after ESS.

Han et al (2014) reported results of the RESOLVE trial, a sham-controlled RCT evaluating the use of office-based placement of a mometasone-eluting nasal stent for patients with recurrence of nasal polyposis after ESS. Eligible patients had chronic rhinosinusitis, had undergone prior bilateral total ethmoidectomy more than three (3) months earlier, had endoscopically confirmed recurrent bilateral ethmoid sinus obstruction due to polyposis that was refractory to medical therapy, and were considered candidates for repeat surgery based on the judgment of the surgeon and patient. Patients and those who administered symptom questionnaires at follow-up visits were blinding to treatment group. The study was powered to detect a between-group difference of at least a 0.6-point change in polyp grade from baseline, and at least a 1.0-point change in nasal obstruction/congestion score. One hundred subjects were randomized to treatment (n=53) or control (n=47). For endoscopically measured outcomes, at 90 days of follow-up the treatment group had a greater reduction in polyp grade compared with the control group (-1.0 vs -0.1; p=0.016) and greater reduction in percent ethmoid obstruction on a 100-mm visual analog scale (VAS; -21.5 mm vs 1.3 mm; p=0.001). For patient-reported outcomes, there were no significant differences in change in nasal obstruction/congestion score between groups. Compared with controls, fewer treatment-group patients required oral steroids for ethmoid obstruction (11% vs 26%) and fewer treatment-group patients were indicated for sinus surgery at 3 months based on established criteria (47% vs 77%), although statistical comparisons are not reported.

Also in 2014, Lavigne et al reported results from a case series of 12 patients who underwent placement of an investigational mometasone-eluting absorbable stent described as similar to the PROPEL device, but with differences in stent structure to target obstructed sinuses, for recurrent

nasal polyposis after ESS. Eligible patients had chronic sinusitis and had undergone bilateral ethmoidectomy more than 90 days before enrollment, but had refractory polyposis on at least one side that was at least Grade 2 on a 0 to 4 point scale. All implants were placed in the office setting. The average SNOT-22 scores (reported as a normalized value with a total possible score that could range from 0-5) changed from 2.19 at baseline to 1.48 at day seven ($p<0.027$), and continued to demonstrate improvements by the six-month follow-up. The mean bilateral polyp grade (clinician-assessed) improved from 4.5 at baseline to 2.8 at day 7 ($p<0.003$), with continued improvements through 6-month follow-up. No significant adverse events were reported.

Also in 2014, Lavigne et al reported results from a case series of 12 patients who underwent placement of an investigational mometasone-eluting absorbable stent described as similar to the PROPEL device, but with differences in stent structure to target obstructed sinuses, for recurrent nasal polyposis after ESS. Eligible patients had chronic sinusitis and had undergone bilateral ethmoidectomy more than 90 days before enrollment, but had refractory polyposis on at least one side that was at least grade 2 on a 0 to 4 point scale. All implants were placed in the office setting. The average SNOT-22 scores (reported as a normalized value with a total possible score that could range from 0-5) changed from 2.19 at baseline to 1.48 at day 7 ($p<0.027$), and continued to demonstrate improvements by the 6-month follow-up. The mean bilateral polyp grade (clinician-assessed) improved from 4.5 at baseline to 2.8 at day 7 ($p<0.003$), with continued improvements through 6-month follow-up. No significant adverse events were reported.

Ow et al (2014) reported plasma mometasone and cortisol concentrations for five patients with recurrent polyposis after bilateral total ethmoidectomy who underwent placement of the same investigational device described by Lavigne et al. Plasma mometasone concentrations were in the undetectable range in 26 of 32 samples at 3, 7, 14, 21, and 30 days postimplant and undetectable in all samples at 21 and 30 days postimplant.

Section Summary: Steroid-Eluting Stents for Recurrent Polyposis

One RCT was identified evaluating the use of steroid-eluting nasal stents for recurrent/persistent nasal polyposis after ESS, which demonstrated improvements in polyp grade and ethmoid obstruction. Strengths of this trial include the use of a sham control and adequate power for its primary outcome. However, the trial is at high risk of bias due to unblinded outcome assessment. Although avoidance of repeat ESS and oral steroids may be a relevant outcome for this indication, it would be important for decisions about repeat ESS or other treatments to be standardized and prespecified or be made by a clinician blinded to treatment group. Sinus stents may prove to have a role in nasal polyposis; however, additional positive results from well-designed RCTs are needed to confirm the results of the single available RCT.

Summary of Evidence

For individuals who have chronic rhinosinusitis who have undergone endoscopic sinus surgery (ESS) who receive implantable steroid-eluting sinus stents, the evidence includes 2 randomized controlled trials (RCTs), a number of observational studies, and systematic reviews of these studies. Relevant outcomes include symptoms, change in disease status, morbid events, and treatment-related morbidity. The most direct evidence comes from 2 RCTs comparing steroid-

eluting sinus stents with non-steroid-eluting stents, both of which showed some benefit with steroid-eluting stents. However, the studies have some limitations, include risk of bias. In addition, because of the comparison group used, these trials primarily evaluate the efficacy of topical steroids when delivered by an implanted device, but do not evaluate the efficacy of the device versus standard care. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have recurrent sinonasal polyposis who receive implantable steroid-eluting sinus stents, the evidence includes one RCT and one single-arm study. Relevant outcomes include symptoms, change in disease status, morbid events, and treatment-related morbidity. The most direct evidence comes from the available RCT, which compared steroid eluting stents plus topical steroids with steroids alone for individuals with recurrent polyposis after ESS. This trial had a high risk of bias due to unblinded outcome assessment. Although avoidance of repeat ESS and oral steroids may be a relevant outcome for this indication, it would be important for decisions about repeat ESS or other treatments to be standardized and prespecified or be made by a clinician blinded to treatment group. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Key Words:

Implantable sinus stents, implantable sinus spacers, PROPEL™, Relieva Stratus™ MicroFlow spacer, Mometasone furoate sinus implant, Sinuva (mometasone furoate)

Approved by Governing Bodies:

The PROPEL™ system (Intersect ENT, Palo Alto, CA) was granted U.S. Food and Drug Administration (FDA) approval under the premarketing approval (PMA) process in August 2011. This device is a self-expanding, bioabsorbable, steroid-eluting stent that is intended for use in the ethmoid sinus. It is placed via endoscopic guidance using a plunger that is included with the device. Steroids (mometasone furoate) are embedded in a polyethylene glycol polymer, which allows sustained release of the drug over an approximate duration of 30 days. The device is dissolvable over a period of several weeks, and therefore does not require removal. In September 2012, a smaller version of the Propel device, the Propel Mini Sinus Implant, was approved for use in patients older than age 18 years following ethmoid sinus surgery.

The Relieva Stratus™ MicroFlow spacer is a balloon-based device that acts as a spacer and medication delivery system which was cleared for marketing under the 510(k) process in October 2011. It is indicated for use as a postoperative spacer to maintain an opening to the sinuses within the first 14 days postoperatively. It is placed via a catheter under endoscopic

guidance. This device is temporary and requires manual removal after 30 days, with implantation of a new device if needed. It is approved for infusion with saline, but not for use with other medications such as steroids. This device is no longer marketed in the U.S.

The SINUVA™ (mometasone furoate) implant is NDA approved (209310) by the FDA, for the treatment of nasal polyps in patients > 18 years of age (18 years of age and older), who have had ethmoid sinus surgery. SINUVA™ is intended as an alternative to sinus surgery in patients with recurrent polyp disease. The SINUVA Sinus Implant is loaded into a Delivery System and placed in the ethmoid sinus under endoscopic visualization. The SINUVA Sinus Implant is made from bioabsorbable polymers designed to gradually soften over time. The SINUVA Sinus Implant may be left in the sinus to gradually release the corticosteroid over 90 days. The SINUVA Sinus Implant can be removed at day 90 or earlier at the physician's discretion using standard surgical instruments.

Benefit Application:

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

Current Coding:

CPT Codes:

0406T	Nasal endoscopy, surgical, ethmoid sinus, placement of drug eluting implant; **(Effective 01/01/2016)**
0407T	; with biopsy, polypectomy or debridement **(Effective 01/01/2016)**

HCPCS Codes:

S1090	Mometasone furoate sinus implant, 370 micrograms

Previous Coding:

Prior to January 1, 2016, there was not a specific CPT code.

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Policy History:

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