Policy Name: Endoscopic Balloon Sinuplasty Ostial Dilation and Steroid-Eluting Sinus Stents for Treatment of Chronic Sinusitis
Effective Date: 9/17/2018

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy
Catheter based endoscopic balloon sinuplasty is COVERED as a stand-alone procedure for treatment of chronic rhinosinusitis in individuals 18 years of age or older.

Catheter-based balloon dilation devices used as assistive instrumentation to gain access to sinuses during standard functional endoscopic sinus surgery (FESS) are considered incidental to the primary FESS procedure and are not separately reimbursable.

Catheter based endoscopic balloon sinuplasty is investigative and unproven and therefore NOT COVERED for all other indications, including but not limited to use in individuals less than 18 years of age. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Drug eluting sinus stents adjunctive to balloon sinuplasty are investigative and unproven, and therefore NOT COVERED. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Note: This policy does not apply to drug eluting sinus stents being used for procedures not associated with balloon sinuplasty. See also related Medica coverage policy, Nasal Implant, Absorbable, for Treatment of Nasal Valve Collapse.

Description
**Balloon Sinuplasty**
Balloon sinuplasty (also known as balloon ostial dilation, balloon dilation sinuplasty, or balloon catheter sinusotomy) is a minimally invasive dilation procedure typically performed by an otolaryngologist. It is suggested for treatment of chronic sinusitis (e.g., rhinosinusitis lasting longer than 12 weeks) associated with inflammatory obstruction of the sinus passages in individuals refractory to conservative medical treatments. The intended outcome is to widen sinus passages (i.e., ostia) and restore normal sinus drainage and function. Balloon dilation devices have been suggested as alternatives to or adjunctive to conventional functional endoscopic sinus surgery (FESS), which...
often requires resection of periosteal bone and tissue. Benefits of balloon sinuplasty are shorter and less traumatic recovery periods, less bleeding, and less postoperative pain than that experienced with conventional FESS.

Patients are first given general or local anesthesia. Then, a sinus guide catheter is inserted into the targeted area, guided by using either fluoroscopy or an illuminated fiberoptic tip. Next, a flexible sinus guidewire is inserted through the catheter and advanced into the targeted sinus, followed by insertion of the balloon catheter. Once in place, the balloon is gradually inflated using a contrast medium and the nasal passage is dilated to between approximately three to seven millimeters. If the achieved dilation is less than desired, an additional dilation may be performed. If needed, dilation of several nasal passages can be done with a single balloon during one session. At postoperative visits, endoscopic evaluation of the sinuses may be performed to assess outcome.

**Drug-Eluting Sinus Stents**
Drug-eluting sinus stents (e.g., Propel®, Propel Mini) are self-expanding bioabsorbable steroid-eluting sinus implants constructed of a synthetic polymer in a lattice pattern. Mometasone furoate (MF) is a topical synthetic corticosteroid with activity against nasal symptoms. The stents are coated with 370 micrograms of MF that is released locally into the mucosal tissue over a 30-day period. They are purported to maintain sinus patency after sinus surgery and/or endoscopic balloon sinuplasty. A surgeon uses a proprietary endoscopic guidance system to advance and position the implants into the desired sinus. Propel and Propel Mini (a shortened version of the Propel) have a lattice-like structure and expand to conform to the anatomy of the modified sinus once they are deployed. Propel and Propel Mini mechanically separate the mucosal tissue and elute a corticosteroid to reduce adhesions, inflammation, edema, and scarring. Intended benefits include reducing the need for postoperative interventions and maintaining the benefits of sinus surgery or balloon sinuplasty.

**FDA Approval**
Balloon ostial dilation devices for treating chronic sinusitis are approved by the FDA under the 510(k) approval process. Examples of FDA-approved endoscopic balloon sinuplasty systems include, but are not limited to:
1. Balloon Sinuplasty™ system (Acclarent, Inc.)
2. FinESS™ Sinus Treatment (Entellus Medical, Inc.)
3. XprESS™ Multi-sinus Dilation Tool (Entellus Medical, Inc.)
4. Vent-Os™ Sinus Dilation System (SinuSys Corporation)
5. Ventera® Sinus Dilation System (ENTrigue Surgical, Inc.).

Drug-eluting sinus stents for maintenance of patency following sinus surgery are approved by the FDA under the Premarket Approval process. Examples of FDA-approved drug-eluting sinus stents include, but may not be limited to:
1. Propel® Sinus Implant (Intersect ENT)

**Prior Authorization**
Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

**Coding Considerations**
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.
CPT Codes:
- 31295 - Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa
- 31296 - Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)
- 31297 - Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)

HCPC Code:
- C2625 – Stent, noncoronary, temporary, with delivery system
- S1090 – Mometasone furoate sinus implant, 370 micrograms

Original Effective Date: 12/1/2007

Re-Review Date(s):
- 12/15/2009
- 1/16/2013
- 7/15/2015
- 7/18/2018
- 10/12/2018 – administrative update; code update
- 2/19/2019 – administrative update; language revision
- 10/16/2019 – administrative update; language revision
- 2/10/2020 – administrative update; format