Sinus Surgery Using Balloon Catheter Instruments 
(*Balloon Sinuplasty Devices*)

**Bullet Points for Physician Advocacy**

As new and emerging technologies become available, it is common for the payor community to label these devices and/or procedures as experimental or investigational. The most effective way to address this issue and establish coverage for a device or procedure is through physician advocacy. Physician advocacy involves educating the payors on the use of the device and/or procedure and establishing the need and demand for access to the technology.

The following bullet points provide a guideline of the topics to discuss with payors when pursuing coverage and payment for balloon catheter technology:

1. **Chronic rhinosinusitis (CRS)** has a substantial negative health impact, resulting in significantly altered physical and social functioning. For 40% to 80% of CRS patients, medical treatment is appropriate and effective. 1-3

2. While functional endoscopic sinus surgery (FESS) is effective in the management of patients with CRS, it is not without its shortcomings.
   a. Adverse events from FESS procedures generally fall under the following categories: 1) hemorrhage, 2) orbital complications including risk of blindness, and 3) cerebrospinal fluid (CSF) leaks.
   b. In recent publications, the overall incidence of adverse events-minor and major- was shown to range from 3.1% to 5.8%. 4-5

3. There are numerous peer-reviewed publications which document that balloon catheter surgical tools are safe and effective in relieving sinus ostial obstruction. (see bibliography below)
   - Patients with chronic rhinosinusitis who failed medical management and were treated in the OR or the office demonstrated a clinically meaningful and statistically significant improvement in symptoms. These improvements were maintained over 6, 12 and 24 months follow-up periods. 6-9
   - Patients experience a low rate of post-operative infections and revisions. 10
   - There is a very low rate of major or minor complications associated with the procedure. 8,10-11
   - Patients undergoing balloon-only surgery require very few (if any) post-operative debridement procedures. This represents a significant reduction relative to previously reported data in FESS procedures. 12
   - The procedure can be performed under local anesthesia without sedation. 7,8
   - After in-office Balloon Catheter Dilation (BCD) under local anesthesia, patients returned to normal activities on average within 2.2 days. 8,13
4. Otolaryngology specialty societies have issued position statements supporting the use balloon catheter technology as an appropriate therapeutic option which is acceptable and safe:

- For American Academy of Otolaryngology (AAO-HNSF) clinical guideline statement which was adopted on 6/28/2010, see: http://www.entnet.org/Practice/Balloon-Dilation.cfm.
- For American Rhinologic Society (ARS) position statement, see http://www.american-rhinologic.org/position_balloon_sinuplasty.
- If state-specific professional society (i.e. AAO) policy statements exist, reference those as well. In addition, reach out to your colleagues at the state society level for their support and/or to mobilize efforts to get the society to submit a letter on behalf of the membership to the payor.
- As of May 2013, ~6,800 surgeons have been trained on balloon technology and Acclarent® Balloon Sinuplasty products have been used in over 275,000 procedures to dilate over 800,000 sinuses. More than 17,000 in-office procedures have been performed.

5. Discuss your own personal experience with balloon catheter tools, whether as a stand-alone procedure or as a tool in FESS. Describe how balloon catheter technology can potentially benefit payors and their member patients.

- Patient outcomes
- Quality of life (QOL)
- Return to normal activities
- Cost (including ability to perform the procedure in a lower cost setting of care and the potential for reduced need for post-operative debridement procedures)

6. Mention that 85% of carriers allow access to balloon technology as a standalone or hybrid procedure. Medicare carriers, most State Medicaid and TriCare provide coverage for the use of balloon catheter technology, as well as most commercial insurers, such as Aetna, Cigna, United HealthCare, Health Net, Humana and many regional carriers. Many more carriers also provide coverage when balloon dilation tools are used as an adjunct to FESS procedures including many BCBSA affiliated plans.

7. Request a peer-to-peer review of the patient’s case by an external reviewer who is an otolaryngologist in current clinical practice.

8. Request a meeting with the Medical Director either face-to-face or over the phone to review current evidence and technology, as well as to discuss patient-specific needs, expected outcomes, and reasons why balloon catheter technology is more appropriate in specific cases.

- Acclarent can provide presentation materials to prepare you for such a dialogue and can also be present for the meeting, if appropriate.
- Consider having the patient available on speaker phone for the discussion or bringing the patient to the meeting.

9. Offer for the Medical Director to come to your practice to view a case. Seeing is believing.
10. Ask specifically for confirmation that existing FESS CPT Codes are appropriate to report when using balloon catheters or other tools in FESS procedures.

11. If the Medical Director insists that balloon dilation cannot be performed as a standalone procedure or used as an adjunct to traditional FESS procedures, ask specifically how you can work with him/her to re-evaluate the current Medical Policy through a review of current published clinical evidence (i.e. “What is a specific date for a possible Medical Policy review?”).

12. Ask to be kept up to date (and involved) as the timeline progresses.

13. If you feel the patient’s case was not given thorough or responsible consideration, consider submitting a formal complaint to the State Department of Insurance.

14. Don’t give up with this payor. Continue submitting requests for coverage and appealing denials. Policies don’t change without clinical demand.