The Business Side of Intragastric Balloon Therapy
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How to Submit a Question

Your Participation

- Please continue to submit your text questions and comments using the Questions panel.

For more information, please [insert contact information]

Note: Today’s presentation is being recorded and will be provided within 48 hours.
Considerations For Your Practice

• Intragastric Balloon (IGB) Requirements
• Determining Price
• Patient self-payment models
• Managing complications
• Marketing
Manufacturer Requirements

• IGB placement information
  – Physician credentialed to perform EGD with biopsy
  – Procedure location and billing address
  – Procedure location contact
  – Product Ordering contact
  – Case scheduling contact
  – Vendor Credentialing
  – Pre-training education
    • Orbera: EMODULE, 60 minute webinar
  – In service training for personnel
Manufacturers Requirements

- Patient care personnel
  - First point of contact
  - Psychologist contact information
    - Does not have to be in office, can be referral
  - Nurse contact information
  - Physician Assistant or Nurse practitioner contact information (not required)
  - Dietitian contact information
    - Does not have to be in office, can be referral
  - Physical Therapist or Exercise Physiologist (not required)
    - Does not have to be in office, can be referral

- Care program
  - Twelve months
  - Minimum contact of once per month
Manufacturer Requirements

• Patient information seminars
• Marketing or PR contact
• Patient Financing
• Complication coverage
• Order – first 10 balloons
• Schedule Training – central training centers
Hospital or Ambulatory Surgical Center Requirements

• Physician credentialing for procedure
  – Must be credentialed for EGD
  – ASGE defines minor skills as those required for using new technology that is a minor extension of an accepted or widely available technique or procedure
    • Placement: extension of balloon dilation or stent placement
    • Removal: extension of foreign body removal
  – IGB placement and removal are minor skills
    • May not require additional granting of privileges
    • Does require certificate of achievement of competence and training from the manufacturer or educational program
• Check with Hospital or Ambulatory Surgical Center Administration

Hospital or Ambulatory Surgical Center Requirements

• Approval for carrying the device
  – Contract required
    • Liability language
    • Liability coverage: many hospitals require a certain minimum of liability insurance coverage for device companies
  – May require “Supply Chain” or equivalent approval
    • Safety
    • Efficacy
Hospital or Ambulatory Surgical Center Requirements

• Facility or anesthesia acuity level
  – ASA classifications accepted
  – Higher ASA class patients may require hospital setting
  – Can perform general anesthesia
• Facility fee
  – Cover the components of the procedure
  – Include cost of general anesthesia for removal and potentially placement
  – Determine comparable codes
    • Balloon dilation, stent placement, foreign body removal
    • Some placement and removal tools are included with the IGB
• Confirm mechanism for patient self-pay
  – If not bundled, consider payment for placement and removal prior to placement
Hospital or Ambulatory Surgical Center Requirements

• Complication coverage
  – Options
    • Patient self pay
    • Supplemental insurance (e.g. Bliss)
    • Included in the bundle
  – Hospital or ASC may mandate coverage and type of coverage
Malpractice Coverage

• Intragastric balloon placement and removal should be listed as a procedure on the policy
• Insurers may add a small charge
• Avoid “non-coverage”
Determining Price

• Fee for Service
  – Some components may be covered by some payers
    • Initial office visit (pre-operative evaluation)
    • MD lifestyle therapy (may only apply to primary care)
    • RD
  – Risks no payment for device removal
  – Risks patients not following up for after care

• Bundled Payment
  – Ensures necessary procedures and visits are paid for in full
  – Easy for patients
  – Consider justification of components of the bundle with comparable codes
Components Included in a Bundle

• Procedure facility fees
  – Consider the needs for possible general anesthesia for removal and placement
• Device stocking fee
• Anesthesia professional fees
• IGB fee (balloons and supplies)
  – Orbera ~$2000
  – ReShape ~$2500
• Endoscopists procedure professional fee
Components Included in a Bundle

- Follow-up care
  - Physician
    - Post-procedure day 1 phone call
    - Post-procedure week 1 office visit
    - Pre-removal visit 1-2 weeks before removal
  - Lifestyle therapy
    - At least one visit per month for 12 months
    - Also consider pre-placement nutrition evaluation
    - Consider adding group visits for behavior therapy
      - Cost effective
      - Group dynamic may have added benefit
Components Included in a Bundle

• Optional
  – Additional lifestyle therapy visits
    • Weight loss correlates with amount of interaction with weight loss team
  – Coverage of complications
    • Severe accommodative symptoms requiring IVF
    • Balloon deflations
    • Serious adverse events: esophageal perforation, gastric perforation, small bowel obstruction, aspiration pneumonia, bleeding
    • Early deflations with replacement of the IGB
    • Consider facility and professional fees
Not Included in the Bundle

• Initial Office Visit
  – Pre-operative evaluation ICD 10: Z01.818
  – Typically covered by insurance despite no benefit for IGB therapy
• 12 month ROV – may be contractually obligated to bill separately
• Pre-operative testing
  – Required: labs
  – Directed by patient symptoms: ECG, Chest X-ray, sleep study
Not Included in the Bundle

• Outpatient medications
  – Anti-emetics
  – Anti-spasmotics
  – Analgesics
  – PPI

• Other referrals
  – Psychology
  – Physical Therapy
  – Other
Not Included in the Bundle

• If complication coverage is not included in the bundle
  – Patient self-pay
  – Additional insurance coverage (Bliss)
    • Hospital will need to accept this insurance
Patient Payment

• We (Washington University in St. Louis, MO) currently do not know of any private third party payer that has IGB benefits

• Consider patient payment documents
  – Advance Beneficiary Notice of Noncoverage for Medicare patients
  – Non-Medicare Patient responsibility form
### Advance Beneficiary Notice of Noncoverage (ABN)

**NOTE:** If Medicare doesn’t pay for D.___________ below, you may have to pay.

Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the D.___________ below.

<table>
<thead>
<tr>
<th>D.</th>
<th>E. Reason Medicare May Not Pay</th>
<th>F. Estimated Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Procedural Visit</td>
<td></td>
<td>$168.</td>
</tr>
</tbody>
</table>

**WHAT YOU NEED TO DO NOW:**
- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the D.___________ listed above.
  - If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

**G. OPTIONS:** Check only one box. We cannot choose a box for you.

- **OPTION 1.** I want the D.___________ listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn’t pay, I am responsible for payment, but I can appeal to Medicare by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.
- **OPTION 2.** I want the D.___________ listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. I cannot appeal if Medicare is not billed.
- **OPTION 3.** I don’t want the D.___________ listed above. I understand with this choice I am not responsible for payment, and I cannot appeal if Medicare would pay.

**H. Additional Information:**

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call 1-800-MEDICARE (1-800-633-4227/TTY: 1-877-486-2048).

Signing below means that you have received and understand this notice. You also receive a copy.

<table>
<thead>
<tr>
<th>I. Signature:</th>
<th>J. Date:</th>
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According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 1 minute per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collected. If you have comments concerning the accuracy of the time estimate and suggestions for improving this form, please write to CMS, 7500 Security Boulevard, Attn: PRA Clearance Officer, Baltimore, Maryland 21244-1850.

Form CMS-R-131 (03/11)  Form Approved OMB No. 0938-0566
Patient’s Name ____________________________
Date of Birth: ____________________________

Washington University Physicians - Department of Internal Medicine
Bariatric Endoscopy Clinic – Shelby Sullivan, MD
1020 N. Mason Rd., Creve Coeur, MO 63141

Insurance Plan Name: ________________________________
Ins Cert# or SSN: ________________________________ Date of Service: ____________________________

Patient Responsibility Form

Based upon available information, it appears unlikely that your insurance plan will pay for the item(s) or service(s) that are described below. The fact that your insurance plan may not pay for a particular item or service does not mean that you should not receive it. Insurance plans typically only pay for services that are specifically defined as covered under your health benefit plan. In addition, plans state that treatment must be considered medically necessary, must fall within frequency guidelines, and must meet any necessary referral or pre-certification requirements.

The purpose of this form is to help you make an informed choice whether or not you want to receive these items or services, knowing that you might have to pay for them yourself. Before you make a decision, you should read this entire notice carefully. If you do not understand why your insurance plan may not pay, you should contact your plan directly.

A. Items or Services: Endoscopic Intragastric Balloon Package
B. Estimated WU Physician’s Fee Cost: $2,900

C. Reason(s) for Denial of Coverage/Payment:

☐ Referral form or approval required by insurance plan has not been provided.

☐ Insurance plan has refused to pre-authorize the items or services listed but patient still wants to receive the item or service.

☐ Non-covered benefit as specified: ____________________________

☐ Not considered medically necessary due to known diagnosis or presenting symptoms of: ____________________________

☐ Not considered medically necessary due to frequency of services: ____________________________

☐ Not considered medically necessary due to pre-operative screening:

☐ Other: Obesity is Primary Diagnosis ____________________________

D. Options:

☐ I want the item/service listed above, please bill my insurance.

☐ I want the item/service listed above, but do not bill my insurance.

Please indicate below that you have decided to receive this service(s) and will be responsible for payment as described above and in the Financial Agreement which notes specific hospital and ancillary items/services and their inclusions or exclusions as part of the procedure package. “I understand that a final decision on whether my insurance plan will pay on the items and services listed above will not be made until my insurance company has received and processed a claim for these services. I realize I can appeal my plan’s decision if no payment is made. If my insurance plan denies payment for the reasons indicated, I agree to be personally and fully responsible for payment of the services noted above.”

Date ____________________________ Signature of patient or person acting on patient’s behalf
Patient Payment

• Direct to you and/or hospital/ASC
  – Account is specific to your therapy
  – General payment accounts could be accessed for payment of services in your group or hospital not related to you

• Financing
  – Direct to patient
  – May require a contract with you or your institution
  – Options
    • Prosper Healthcare lending
    • Care Credit
  – Qualification done on line
  – Variable rates and loan repayment schedules
Patient Payment

• Complications
  – Not covered by primary insurance
  – Options for coverage
    • Include fee in the bundle: global fee
    • Contract with third party ($300-$500)
      – 30 day
      – 6 month
    • Patient self pay
Marketing

• Develop a press release for local media
  – Institution: work with your PR department
  – Private practice: consider joint hospital or ASC release
  – Coordinate with device company on any mention of their product

• Advertise
  – Materials from sponsors available
Marketing

• Network
  – Primary care physicians
  – Orthopedic surgeons
  – Plastic surgeons
  – Endocrinologists
  – Cardiologists
  – Obstetricians
  – Reproductive endocrinologists
Marketing

• Offer patient seminars
  – No or small fee to attend
  – In person or webinar
  – Review the therapy, risks, benefits, and alternatives
  – Set the tone for non-judgmental therapy and patient relationship
Checklist

• Intragastric balloon requirements
  – Meet manufacturer’s requirements
    • Pre and Post care team identified
    • Patient financing
    • Complication coverage
    • Marketing plan
    • Order
    • Training
  – Hospital /ASC requirements
    • Authorization to carry balloons
    • Permission to form placement and removals
    • Negotiate facility fee
    • Mechanism for self-payment
    • Mechanism for managing complications
    • Malpractice coverage
Checklist

• Determining price
  – Lifestyle therapy
  – Coverage of complications
  – Facility and professional fees

• Payment models
  – Bundle vs incident of care billing

• Method for managing complications

• Marketing plan
Questions?