

# **Request for Reassignment of Solesta<sup>®</sup> Procedure to a new APC**

**Hospital Outpatient Payment (HOP)  
Advisory Panel Meeting  
March 10-11, 2014**



# Topics and Presenters



Description of the Issue

Clinical Description

CPT/HCPCS Codes

APCs Impacted

Recommendation and Rationale for Change

Potential Consequences

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# Description of the Issue



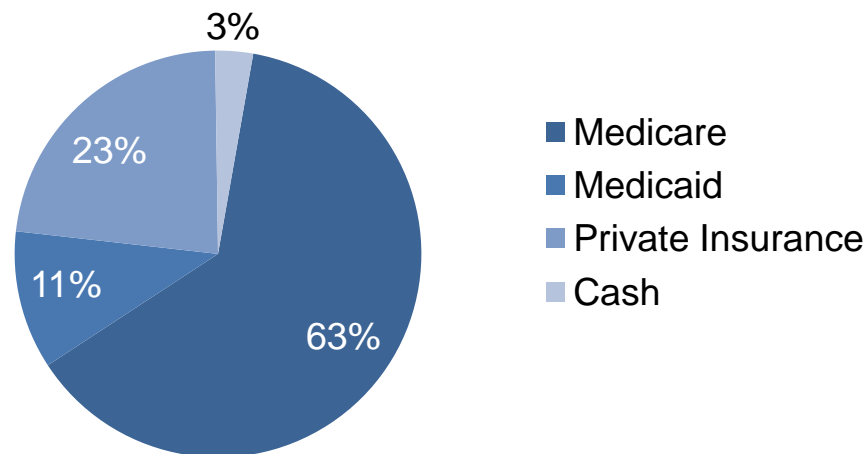
- ◉ APC assignment of C9735 is inappropriate, as the payment rate for APC 0150 is inadequate to cover the costs of the Solesta procedure
  - ▶ Current payment rate for APC 0150: **\$2,501.31**
  - ▶ Calculated geometric mean cost for C9735: **\$5,372.86\***
- ◉ Current APC payment rate does not fully take into consideration the costs associated with the procedure's required resources
  - ▶ The Wholesale Acquisition Cost (WAC) for one carton of four 1-mL syringes alone is **\$4,900**
  - ▶ Beyond the cost of Solesta, the approximate overhead costs include\*\*:
    - \$450- procedure room overhead
    - \$100-ancillary clinical staff
    - \$50-other equipment and supply costs
- ◉ CMS assigned Solesta an L code, thus designating it as a prosthetic implant, instead of the proposed J code, for drugs
  - ▶ As a result, instead of providers receiving separate payment for Solesta, payment is now packaged into the payment for the primary procedure
- ◉ CMS has denied past requests for Solesta to be considered for a New Technology APC

# Fecal Incontinence: Patient Population and Health Economics



- Fecal Incontinence (FI) is defined as the accidental loss of solid or liquid stool<sup>1</sup>

**Payer Mix for Fecal Incontinence<sup>2</sup>**



- ▶ The average annual cost to patients with FI is \$4,110<sup>3</sup>
- ▶ Direct medical and non-medical costs average \$2,562, with surgical costs up to \$30,000<sup>4</sup>

1. Dunivan GC, Heyman, S, Olafur, SP, et al. Fecal Incontinence in primary care: prevalence diagnosis, and health care utilization. *American Journal of Obstetrics*. 2010 May;493.e1  
2. S, et al. *Dis Colon Rectum*. 2012 May;55(5):586-98.  
3. *Ibid*, 3. Weighted national estimates form HCUP Nationwide Inpatient Sample (NIS), 2009, Agency for Healthcare Research and Quality.  
4. Medtronic. InterStim Therapy for urinary and bowel control. Common Billed Codes, January 2012

# Clinical Description of Solesta<sup>®</sup> Procedure



- Solesta is a biocompatible, injectable gel, consisting of dextranomer microspheres in stabilized hyaluronic acid
  - ▶ indicated for the treatment of FI in patients 18 years and older who have failed conservative therapy



- One treatment includes anoscopy with four separate *submucosal* injections into the anal canal
  - ▶ Above the dentate line
  - ▶ Most patients undergo only one treatment

# Solesta Fills an Unmet Clinical Need



Patient diagnosed with FI



## Conservative Therapies

- Diet/fiber
- Stool softeners
- Anti-motility
- Anti-diarrheals
- *Generally safe*
- *Limited success rates*
- *Patients may not wish to proceed to surgery*
- *Patients may not be candidates for surgery*

## Solesta®

- **Non-surgical treatment, outpatient procedure**
- **No anesthesia required**
- **Patients may resume limited physical activity immediately**
- **Unlikely to impede future procedures**
- **Proven safety and efficacy in clinical trials**

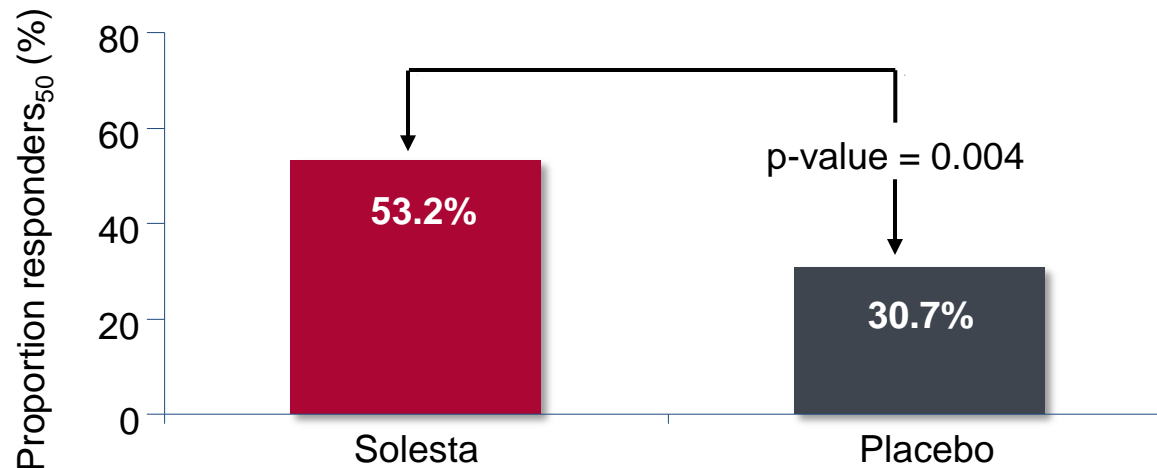
## Surgical Therapies

- Anal sphincter repair
- Sacral nerve stimulation
- Colostomy
- Antegrade colonic enema
- Graciloplasty
- SECCA®
- *Invasive*
- *Prolonged recovery*
- *General anesthetic*
- *Potential safety issues*

# Solesta is Safe and Effective



- Multicenter, randomized, double-blind study evaluating the safety, efficacy and durability of Solesta against a placebo<sup>5</sup>

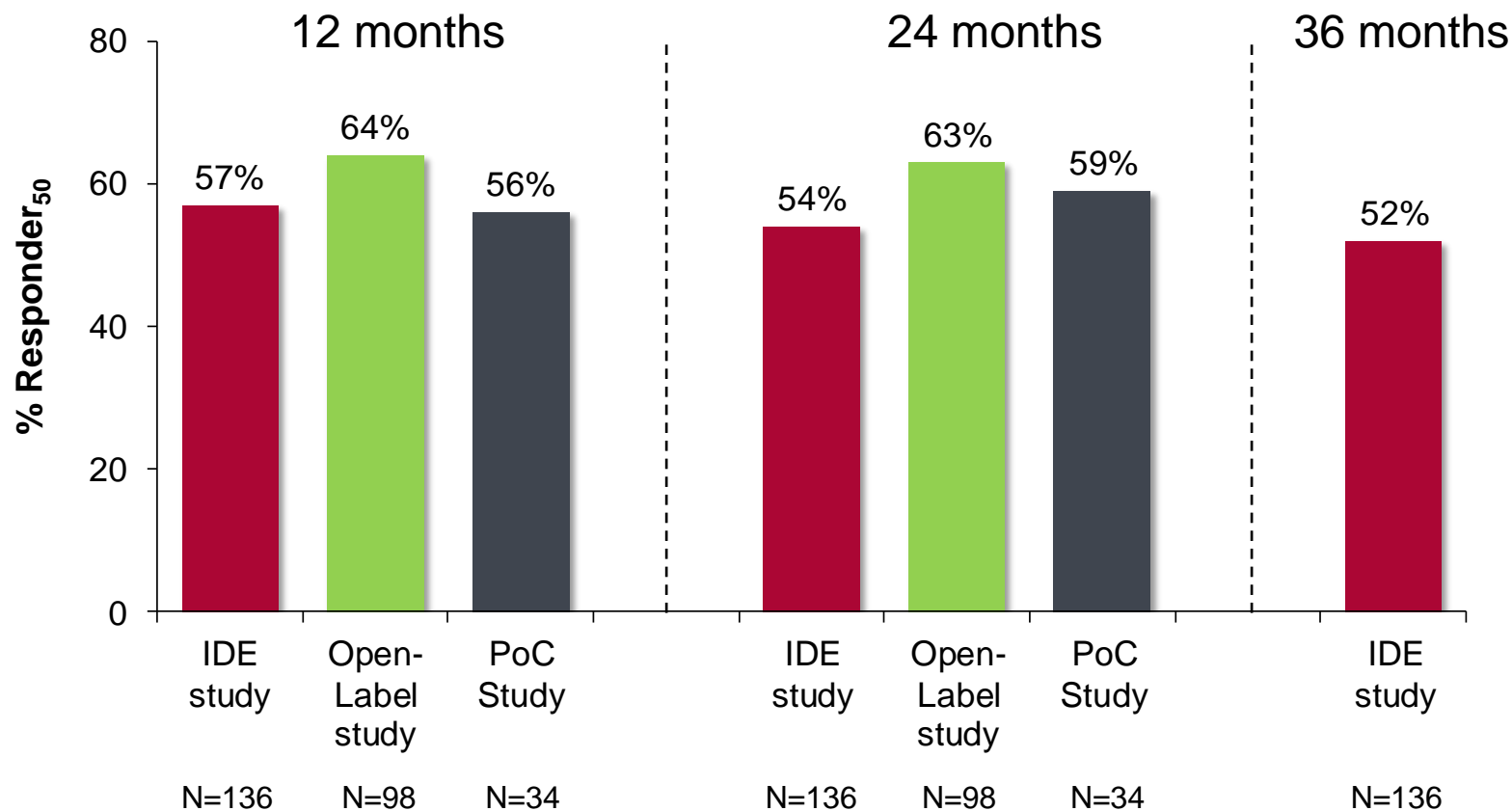


- Patients using Solesta had almost a 2-fold increase of incontinence free-days
- Research shows that there are other patients who have a higher response rate than just meeting the responder<sub>50</sub> criteria<sup>6</sup>

5. Graf W, Mellgren A, et al. *Lancet*. 2011 ;377(9770):997-1003.

6. Graf. W, Wester T, et al. Efficacy and quality of life 2 years after treatment for faecal incontinence with injectable bulking agents. *Tech Coloproctol* (2013) 17:389-395

# Consistent Response to Solesta Across Clinical Studies<sup>7,8</sup>



7. Solesta [package insert]. Raleigh, NC. Salix Pharmaceuticals, Inc.; 2011.

8. Data on file. Salix Pharmaceuticals, Inc.



# Current Coding and Reimbursement for Solesta Procedure



- ⦿ The following HCPCS codes are used to bill for the Solesta procedure:

HCPCS Code	Description	SI	OPPS Payment	
			APC	Payment Rate
C9735	Anoscopy; with directed submucosal injection(s), any substance	T	0150	\$2,501.31
L8605	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal, per 1 mL	N	--	--

- ⦿ C9735 is used to describe the procedure itself
  - ▶ Effective April 1, 2013
  - ▶ Assigned to APC 0150 (Level IV Anal/Rectal Procedures)
- ⦿ L8605 is used to describe the materials used (Solesta)
  - ▶ Not separately reimbursed in the HOPD or ASC settings

# Recommendation for Change



- ◎ CMS should consider creating a **new APC for Level V Anal/Rectal Procedures** and include C9735, as well as the following procedures:
  - ▶ CPT code 46762 (Sphincteroplasty, anal, for incontinence, adult; implantation artificial sphincter)
  - ▶ CPT code 0184T (Excision of rectal tumor, transanal endoscopic microsurgical approach (ie, TEMS) including muscularis propria (ie, full thickness))

Proposed APC	Relative Weight	Payment Rate
New Level V Anal/Rectal Procedures (C9735, 46762, 0184T)	57.1477	\$4,153.04
Revised Level IV Anal/Rectal Procedures (current codes, minus C9735, 46762, 0184T)	33.7079	\$2,449.62

- ◎ This change would have minimal impact on the payment rate associated with the Revised Level IV Anal/Rectal Procedures, as the payment rate would decrease by \$51.71

# Rationale for Change



- This new APC should include CPT/HCPCS codes 46762, 0184T, and C9735 as the geometric mean costs for these procedures are much higher than other procedures in APC 0150

HCPCS Code	SI	APC	Payment Rate	Single Frequency	Total Frequency	Minimum Cost	Maximum Cost	Median Cost	Geometric Mean Cost	CV
46762	T	0150	\$2,501.31	8	13	\$2,694.85	\$15,524.04	\$11,801.23	\$10,292.98	36.568
C9735	T	0150	\$2,501.31	n/a	n/a	n/a	n/a	n/a	\$5,372.86	n/a
0184T	T	0150	\$2,501.31	104	155	\$1,095.83	\$9,521.53	\$3,918.83	\$3,887.58	42.026
46761	T	0150	\$2,501.31	8	39	\$1,933.12	\$5,423.38	\$2,697.52	\$2,975.53	37.008
46707	T	0150	\$2,501.31	122	166	\$1,017.76	\$7,449.57	\$3,102.72	\$2,898.07	31.989
45560	T	0150	\$2,501.31	268	796	\$834.35	\$9,862.30	\$2,682.70	\$2,832.85	50.668
46288	T	0150	\$2,501.31	83	140	\$742.05	\$5,237.77	\$2,390.79	\$2,287.70	36.531
45541	T	0150	\$2,501.31	151	353	\$119.31	\$19,627.03	\$2,678.69	\$2,794.29	100.422
46750	T	0150	\$2,501.31	54	195	\$1,110.59	\$11,155.99	\$2,539.86	\$2,633.64	65.531
0249T	T	0150	\$2,501.31	74	146	\$981.30	\$6,831.87	\$2,695.72	\$2,610.69	36.75
46947	T	0150	\$2,501.31	1476	2255	\$867.29	\$6,842.82	\$2,404.72	\$2,414.68	32.094
45172	T	0150	\$2,501.31	395	591	\$713.35	\$6,745.61	\$2,229.07	\$2,271.28	43.879
0288T	T	0150	\$2,501.31	6	6	\$1,506.26	\$3,198.29	\$2,013.49	\$2,172.63	30.955
45505	T	0150	\$2,501.31	77	277	\$569.16	\$7,037.66	\$2,280.93	\$2,062.75	48.79
46760	T	0150	\$2,501.31	5	9	\$62.94	\$4,058.92	\$348.16	\$379.28	163.415

# Collecting Cost Data for C9735



- ◉ Since HCPCS code C9735 became effective April 1, 2013, cost data is not yet available
- ◉ Salix is working to obtain claims data to further support the costs for performing the Solesta procedure, which warrant a higher reimbursement rate than what is assigned to APC 0150

# Potential Consequences



- ◎ The current payment rate for the Solesta procedure jeopardizes its adoption as a clinically meaningful procedure for Medicare beneficiaries who could benefit from its use
  - ▶ The Solesta procedure is a safe and effective treatment which fulfils an unmet need within the spectrum of care for patients with FI, who have limited treatment options
  - ▶ Without adequate reimbursement for the Solesta procedure, providers may be less inclined to provide access to this treatment
  - ▶ Without Solesta, patients are left with costly, invasive procedures, or conservative therapies which may not adequately treat symptoms
- ◎ Continued inappropriate reimbursement for procedures represented by CPT codes 46762 and 0184T



# Questions and Discussion