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## Background and Objective

Percutaneous transluminal septal myocardial ablation (PTSMA) is an alternative to surgery for left ventricular outflow tract obstruction in patients with hypertrophic obstructive cardiomyopathy (HOCM). In HOCM, thickened heart muscle obstructs proper blood flow.

PTSMA involves injection of dehydrated alcohol into the coronary artery inducing a localized basal septal myocardial infarction which remodels the outflow tract.

Ablysinol, a dehydrated alcohol product, was first approved by the US Food and Drug Administration (FDA) on June 21, 2018.

Ablysinol approval might have affected the number of PTSMA procedures conducted and subsequent procedural complications.

**Objective:** To examine frequency of PTSMA and common procedural complications before and after approval of Ablysinol using the FDA Sentinel System

## Methods

### Study population

Patients aged ≥ 18 years who had PTSMA in inpatient (IP) and outpatient (OP) settings identified in the FDA Sentinel System

- Prior to Ablysinol approval (January 01, 2016- June 21, 2018)
- After Ablysinol approval (June 22, 2018- June 30, 2022)

- Inpatient and outpatient PTSMA procedures defined separately using ICD-10-PCS or CPT-4, Category I codes (Box 1)

- Continuous medical and drug coverage, for at least 183 days prior to index PTSMA required, gaps in coverage of up to 45 days allowed

- NDC codes for Ablysinol or dehydrated alcohol on the PTSMA procedure date or in the 5 days before or after examined

### Box 1: PTSMA procedures codes

Code	Description	Code type	Setting
93583	Percutaneous transcatheter septal reduction therapy (eg, alcohol septal ablation) including temporary pacemaker insertion when performed	CPT-4	IP/OP
025M3ZZ	Destruction of Ventricular Septum, Percutaneous Approach	ICD-10-PS	IP/OP

Cohort entry: first PTSMA between January 1, 2016 - June 30, 2022

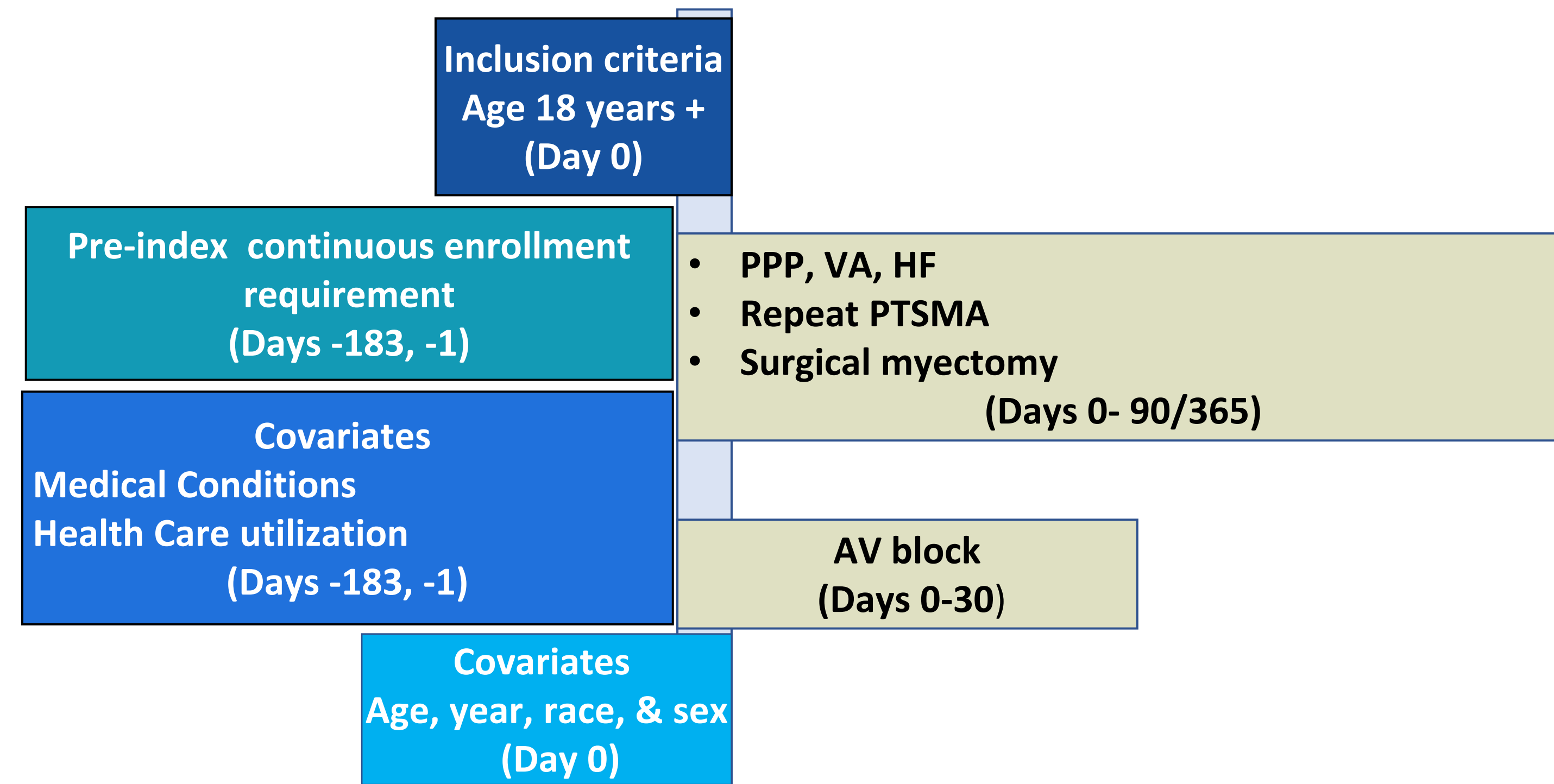


Figure 1. Study Design Diagram

### Outcomes

Potential PTSMA complications:

- permanent pacemaker placement (PPP)
- ventricular arrhythmia (VA)
- heart failure (HF)
- myocardial infarction (MI)
- atrioventricular (AV) block (up to 30 days post procedure)

repeat PTSMA, and surgical myectomy were examined in the 90 and 365 days post PTSMA procedure

Table 1: Settings for outcome identification

	Any setting	Inpatient only	Inpatient or ED
PPP	X		
VA			X
AV block	X		
HF			X
MI			X
Repeat PTSMA	X		
Surgical myectomy		X	

## Results

### PTSMA procedures

- 3099 patients with PTSMA procedure identified
- **January 2016-June 2018**
  - 818 total, 307 inpatient (37.5%) , 511 outpatient (62.4%)
- **June 2018 to June 2022**
  - 2281 total, 1177 inpatient (51.6%) 1104 (48.3%) outpatient procedures
- Trend of increasing PTSMA procedures per year in both settings (Table 2)
- No NDC codes identified for Ablysinol or dehydrated alcohol on the date of the PTSMA procedure or in the 5 days before or after

Table 2: PTSMA procedures by setting and year

Year	Patients with PTSMA		
	All Settings N=3099	Inpatient N=1484	Outpatient N=1615
2016	285	120	165
2017	348	126	222
2018	409	157	252
2019	622	339	283
2020	569	306	263
2021	692	358	334
2022	174	78	96

### Potential PTSMA complications

- Most common potential procedural complications in both settings and study periods were:
  - AV block (specifically 3rd degree AV block)
  - HF
  - PPP
  - VA
- Most occurred within 90 days of index procedure, no major increase after extending follow up to 365 days
- The proportion of patients experiencing AV block (total 47.6% to 56.3%), HF (total 43.3% to 52.5%), and PPM (total 25.2%-33.0%) increased slightly after approval of Ablysinol (Figure 2).
- Surgical myectomy rare and repeat PTSMA uncommon
  - Repeat PTSMA procedures increased (4.8% to 8.2%), after approval of Ablysinol

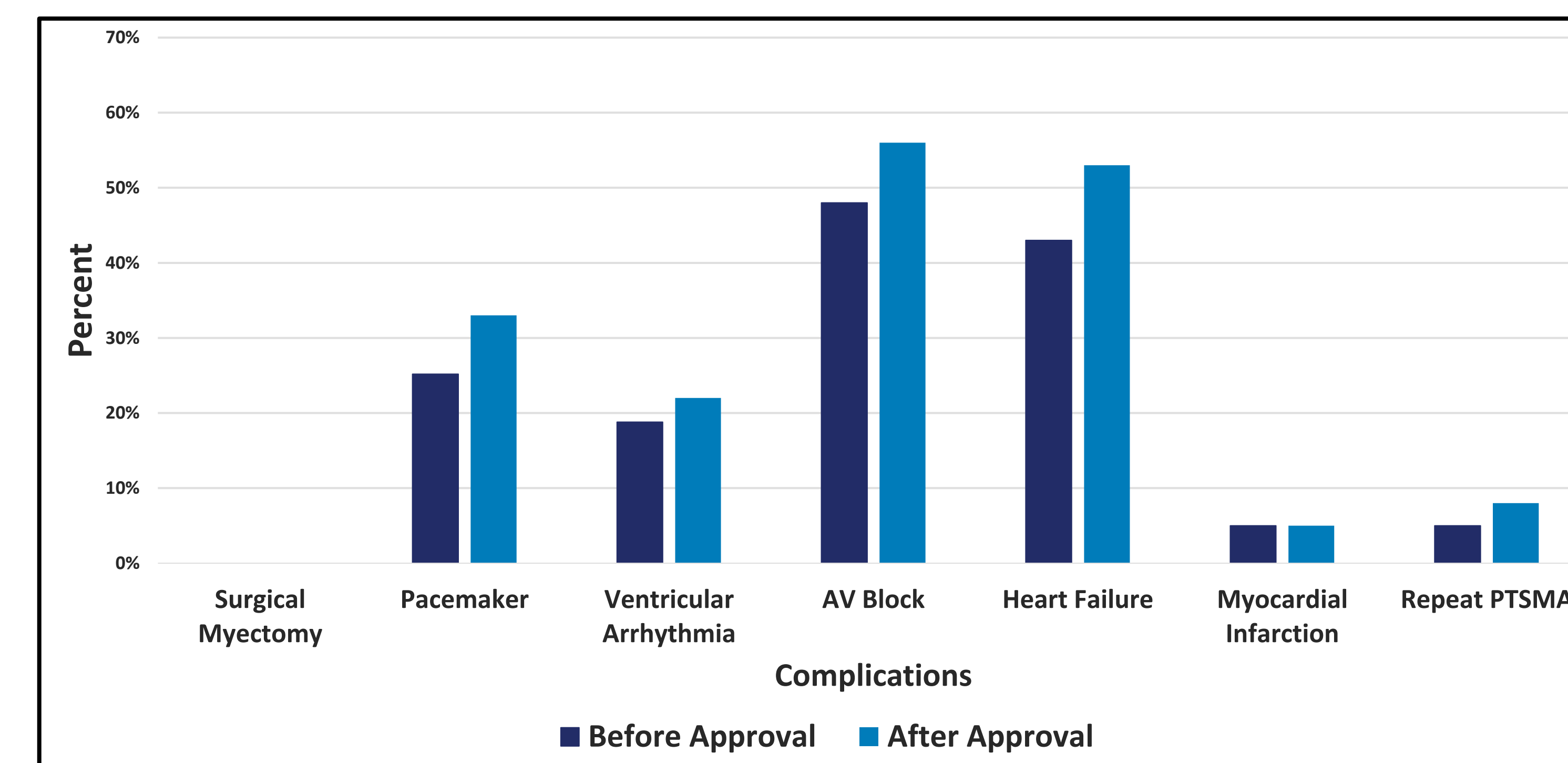


Figure 2: 90 Day potential PTSMA Complications

## Discussion and Conclusions

Trend of increasing frequency of PTSMA procedures per year in both settings.

- Increases after Ablysinol approval were small and not concerning.

Most common potential PTSMA complications: AV block (specifically 3rd degree AV block), HF, PPP, increased slightly after approval of Ablysinol.

Repeat PTSMA procedures increased after approval of Ablysinol (4.8% to 8.2%), despite being relatively uncommon.

Ablysinol use was not captured separately in claims data, likely rolled up into procedure claim.

This study represents a novel use of the FDA Sentinel System to examine potential changes in medical procedures, before and after FDA approval of a product used in the procedure.