

Budget impact analysis of capsule endoscopy for scheduled monitoring in Crohn's Disease

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Objectives: Crohn's disease, a chronic inflammatory condition of the gastrointestinal tract, is associated with substantial healthcare costs. Endoscopic inspection is considered essential for monitoring and optimizing treatment. Ileocolonoscopy visualizes the colon and terminal ileum but additional imaging is required to evaluate the entire bowel. Small bowel and colon capsule endoscopy (SBC-CE) evaluates the entire small bowel and colon in a single assessment. This analysis considers whether use of SBC-CE could reduce costs.

Methods: A patient-level, discrete-event simulation evaluated care and costs (in 2016 USD) in 1,000 patients (representing 140,184 patients in the health plan) over 5 years. During each cycle, patients were exposed to the risk of disease progression, adverse events, surgery, and death. Disease state changes used underlying Markov models for development of ulcers, stricturing, rectal disease, and anatomic involvement. Treatment decisions were reviewed every 3 months using patient-reported information and marker assessment or results from endoscopic monitoring. Monitoring was performed every 3, 6, or 12 months for patients starting treatment, presenting with symptoms, or in remission, respectively.

Results: SBC-CE resulted in a lower total cost of care (-1.1%, -\$169.2 million). Monitoring costs (-8.3%), adverse events costs (-2.6%), and treatment costs (-0.4%) were reduced with SBC-CE compared with ileocolonoscopy. SBC-CE identified more patients with non-symptomatic disease, moving them to treatment more efficiently. Sensitivity analyses demonstrated that model results were robust to sampled changes in input parameters, with SBC-CE resulting in a reduced total cost of care in 82.4% of simulations and a median cost saving of \$1,622 per patient.

Conclusions: Use of SBC-CE for monitoring of Crohn's disease can result in reduced healthcare costs. Savings are generally realized in the cost of monitoring and avoidance of adverse events associated with ileocolonoscopy.

BACKGROUND

- Crohn's disease is an Inflammatory Bowel Disease (IBD) commonly presenting at the end of the small bowel (terminal ileum) or the start of the colon
- About 33,000 cases of Crohn's disease are diagnosed each year in the USA [1]
- The burden of Crohn's disease in the USA is extensive:
 - Crohn's disease increases healthcare costs by circa \$7,500 versus control patients [1]
 - The total annual burden of Crohn's disease was found to be \$3.48 billion in national costs [1]

CROHN'S DISEASE MONITORING

- Endoscopic inspection is considered essential [2]
 - Ileocolonoscopy cannot assess the small bowel and has been shown to be miss active disease in the terminal ileum [3]
 - Ileocolonoscopy is often complemented by magnetic resonance enterography (MRE) or computed topography (CT)
- For complete endoscopic evaluation of the digestive tract, small bowel and colon capsule endoscopy (SBC-CE) is now available

AIMS

- To quantify the budget impact of switching Crohn's patients from monitoring with ileocolonoscopy ± MRE/CT to SBC-CE

METHODS

Data identification

- Structured searches of PubMed were performed to identify publications relating to the incidence and costs of Crohn's disease, related adverse events (AEs), and treatment
 - Title/abstract searches and MeSH terms restricted hits to abstracts on IBD
 - Searches were performed on November 7, 2016
- Costs of monitoring were taken from the Medicare 2016 fee schedule

Budget-impact model

- A patient-level, discrete-event simulation evaluated care and costs (in 2016 USD) in 1,000 simulated patients over 5 years
 - At each 3-month cycle, patients were exposed to the risk of disease progression, adverse events, surgery, and death
 - A Markov model for mucosal healing/deterioration simulated development of ulcers, stricturing, rectal disease, and anatomic involvement
- Monitoring was every 3, 6, or 12 months for patients starting treatment, presenting with symptoms, or in remission, respectively.
 - When not used in a cycle, patient-reported information and marker assessment (PRIMA) informed treatment decisions
- Treatment was assigned dependent on patient risk-levels

Base case

- 140,184 Crohn's disease patients in the health plan [4]
 - Mean characteristics of age 42 years, 43.5% male, weight 83.6 kg, and CDAI score of 220 points [5,6]
- The performance (sensitivity and specificity) and cost of monitoring modalities is presented in Table 1
 - Monitoring AEs included SBC-CE retention in 2% of cases and, for ileocolonoscopy: gastrointestinal bleeding (0.42%) and bowel perforation (0.08%) [7-9]
- Monitoring was 90% ileocolonoscopy and 10% SBC-CE in the standard of care arm, whereas 50% of monitoring visits used SBC-CE in the comparator arm
 - The SBC-CE market share increased by 10% per annum
 - MRE/CT monitoring was used in conjunction with monitoring for L3-L4 disease, it was added to all ileocolonoscopies and 20% of SBC-CE
- Treatment options for active disease were Vedolizumab, Natalizumab, Infliximab, and corticosteroids
 - Respective market share (%) ranged from 10:10:20:60 in low-risk patients to 25:25:30:20 in high-risk patients
- The model time horizon was 5 years with 3.5% annual cost discounting

Sensitivity analyses

- Probabilistic analysis evaluated the robustness of results to changes in input parameters
 - 500 samples of 200 bootstrapped patients provide median and 95% credible intervals (CrI)

Table 1. Effectiveness and cost of monitoring modalities

Monitoring	Sensitivity	Specificity	Cost [†] , USD
PRIMA	67% [10]	44% [10]	0.00
Ileocolonoscopy	90% [11]	100% [11]	946.10
MRE	77% [12]	80% [12]	296.16
CT	89% [13]	80% [13]	364.68
SBC-CE	93% [14]	84% [14]	938.70

CT, Computed topography; MRE, Magnetic resonance enterography; PRIMA, Patient-reported information and marker assessment; SBC-CE, Small bowel and colon capsule endoscopy (specifically PillCam, Medtronic). [†] Costs from Medicare 2016 fee schedule; SBC-CE uses code 91110

RESULTS AND DISCUSSION

- In the base case, the total cost of care for Crohn's disease was estimated at \$15.57 billion over 5 years (Table 2)
 - The mean annual cost of care per patient was \$21,757 (Table 2), in the \$18,637 to \$22,796 range found by Park et al [15]
 - As in [15], treatment costs, in particular the use of biologics, were the main cost driver, accounting for 85.8% of total costs
- In the comparator arm with 50% SBC-CE use, the total cost of care was reduced to \$15.40 billion over 5 years (Table 2)
- The saving was \$169.2 million over 5 years, or \$236 per patient per year

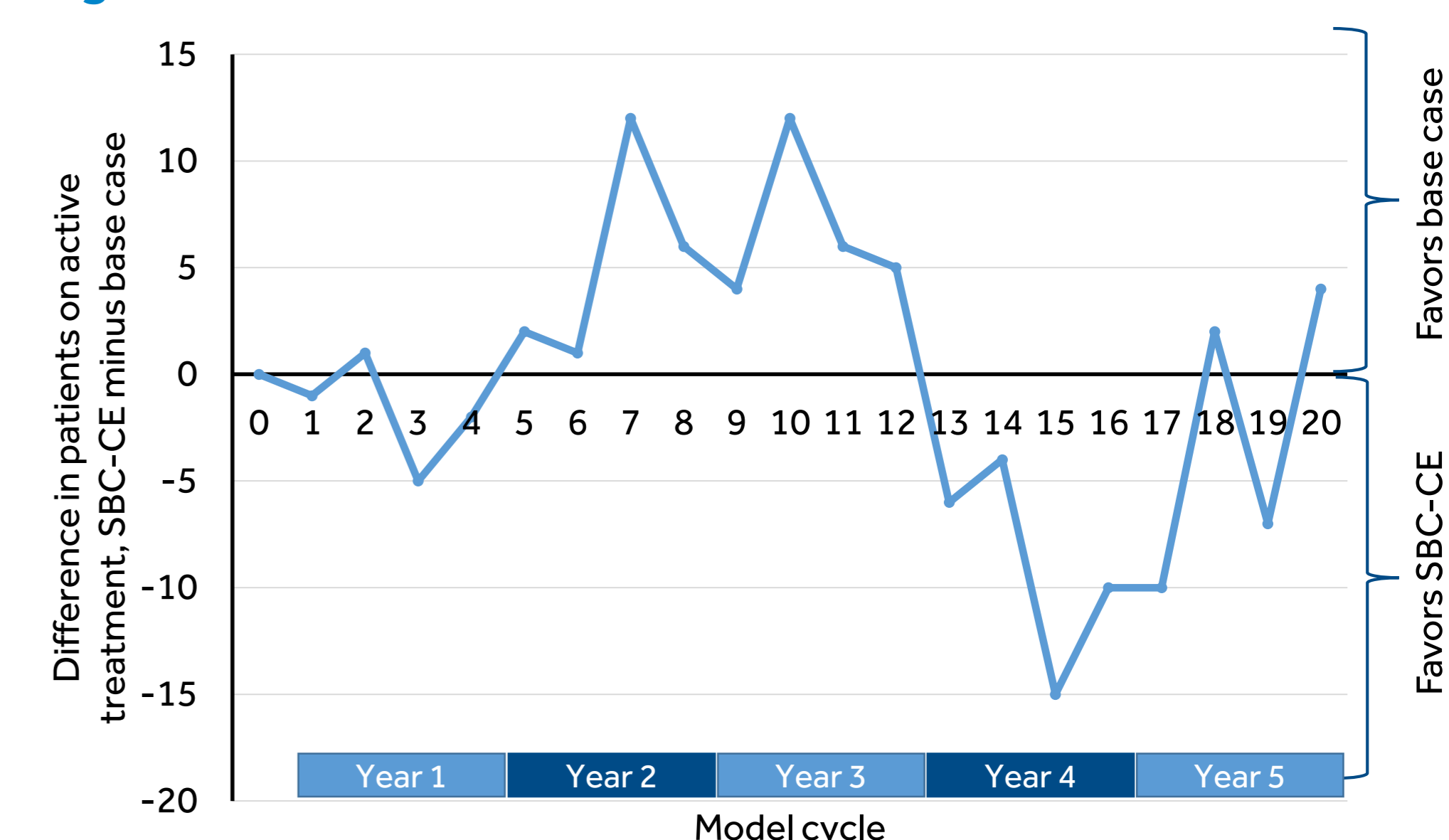
Table 2. Base case results

Cost outcomes at 5 years, USD	10% SBC-CE	50% SBC-CE
Total	\$15.57 billion	\$15.40 billion
Monitoring	\$932 million	\$854 million
Treatments	\$13.35 billion	\$13.29 billion
Adverse events	\$1.28 billion	\$1.25 billion
Total per patient year	\$21,757	\$21,521

SBC-CE, Small bowel and colon capsule endoscopy

- The largest saving (\$77.7 million) came from reduced monitoring costs
 - Monitoring costs were 8.3% lower with 50% SBC-CE as compared with the base case
 - Reduced use of imaging: MRE and CT, with SBC-CE helped to reduce monitoring costs
- Treatments accounted for a higher proportion of total costs (86.3% versus 85.8%) with 50% SBC-CE than in the base case
 - Overall, patients spent less time on treatment with SBC-CE compared with the base case
 - Compared with the base case, treatment use with SBC-CE was higher in the first 3 years of the model, and then reduced in the final two years (Figure 1)

Figure 1. Use of treatments over the model time horizon

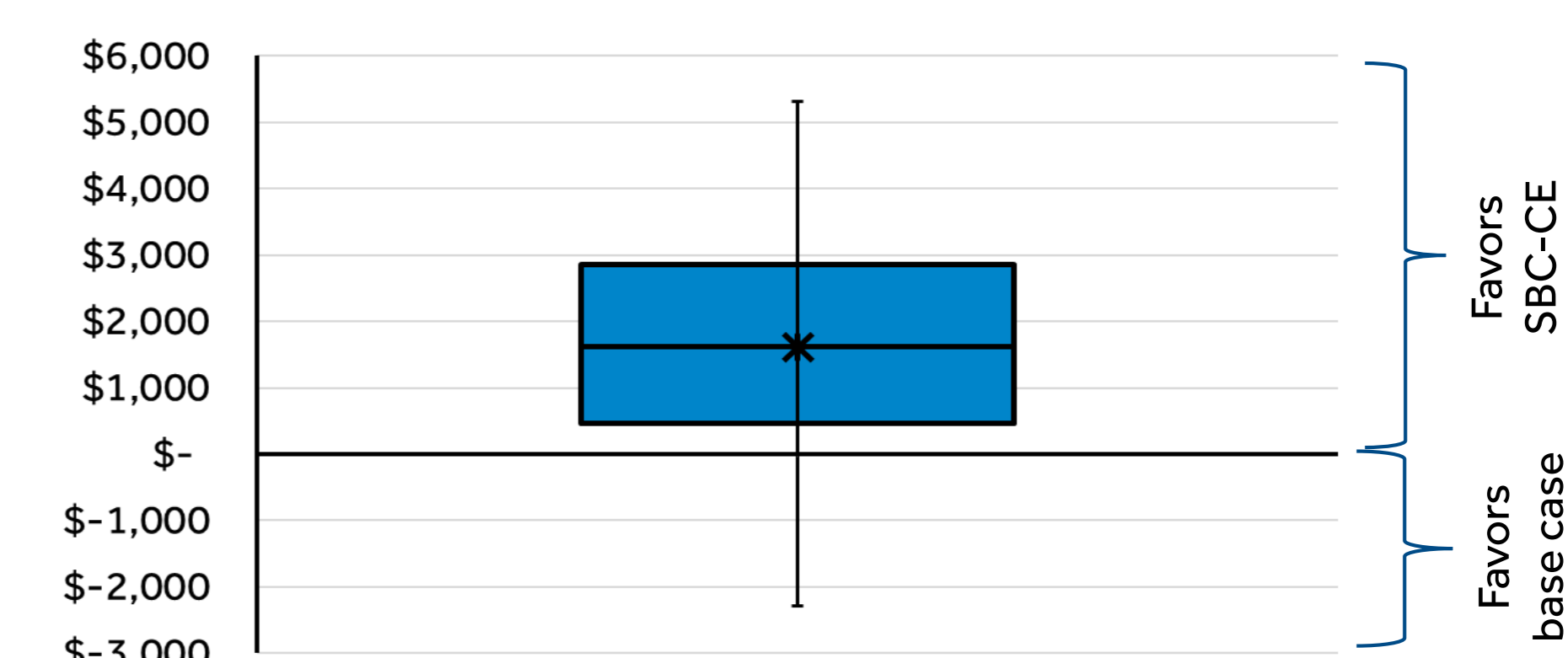


- Higher sensitivity of SBC-CE may have resulted in more patients with active disease being assigned to treatment early in the model
 - Being identified earlier, the likelihood of treatment success was increased and may have driven lower treatment use in later cycles

Sensitivity analyses

- SBC-CE was cost saving in 82.4% of bootstrap populations, the median (95% CrI) per patient savings over 5-years was \$1,622 (-\$2,289 to \$5,316; Figure 2)

Figure 2. Range of mean five-year per patient savings



Scenario analyses

- Sensitivity and specificity values vary by publication, using different values for SBC-CE resulted in substantial changes in savings (Table 3)
- Biosimilars for Crohn's disease treatment are expected soon, accounting for a 30% cost decrease in these agents resulted in a \$150 million dollar saving at 5-years (Table 3)

Table 3. SBC-CE performance influences cost savings

Scenario, reference	Sensitivity	Specificity	Biologic price	5-year cost saving, USD
1 [16]	89%	100%	100%	517.6 million
2 [17]	100%	91%	100%	212.7 million
3 [14]	93%	84%	70%	150.0 million

CONCLUSIONS

- Healthcare costs associated with Crohn's disease were reduced by use of pan-intestinal SBC-CE for monitoring
- Using SBC-CE, diagnosis of active disease in the terminal ileum and small bowel is possible without need for MRE/CT
- Adverse events associated with ileocolonoscopy are avoided, leading to cost savings for SBC-CE

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- A newer version of the presented model is available, with results consistent with those presented here

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