



Minimally Invasive Therapies Group

Gastroenterology and Hepatology
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**Novitas
Open Meeting
September 11, 2020**

RE: Proposed Local Coverage Determination Category (LCD): Colon Capsule Endoscopy (DL38807)

Presenter: Francesca Rancati, PhD

Presenter Talking Points

- Medtronic appreciates the effort that went into the development of the proposed LCD Colon Capsule Endoscopy (CCE) (DL38807)
- We appreciate, in particular, Novitas’ recognition that PillCam™ COLON 2 qualifies for Medicare coverage as a diagnostic test, that it is safe and effective, as well as reasonable and necessary for a defined patient population
 - CCE is a suitable alternative to OC or CTC as a primary procedure in patients with major risks for OC or moderate sedation or as a secondary procedure for surveillance of colon polyp(s) in previously diagnosed patients where OC was incomplete or was contraindicated.
 - CCE is suitable as a secondary procedure when an incomplete diagnostic OC was performed for either fecal occult blood test (FOBT) positive (guaiac or immunochemical) or for multi-target stool DNA (sDNA) test positive.
- The proposed LCD indicates that CCE is not a Medicare Benefit for colorectal cancer screening, regardless of family history or other risk factors for the development of colonic disease
 - Medtronic supports this limitation as PillCam COLON 2 is not FDA approved for colorectal cancer screening
- Medtronic respectfully requests Novitas move forward with coverage of Colon Capsule Endoscopy based upon the FDA approved indications