KAISER PERMANENTE® Mid-Atlantic States	**Capsule Endoscopy Medical Coverage Policy**

Utilization *ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document
- Please refer to Medicare Coverage Database requirements for wireless capsule or video endoscopy determinations for Medicare members.
- Note: After searching the Medicare Coverage Database, if no NCD/LCD/LCA is found, then use the policy referenced above for coverage guidelines

I. **Specialties:** Primary Care, Internal Medicine, Gastroenterology
Related Medical Coverage Policies: Virtual Colonoscopy

II. **Indications for coverage**

A. Diagnosis of small intestine bleeding of obscure etiology with objective evidence of bleeding with one or more of the following:

1. Positive, persistent fecal occult blood testing or
2. Iron deficiency anemia or
3. Blood loss visualized in the rectum **AND** gastrointestinal bleeding source has not been identified with both of the following tests:
    a. Esophagogastroduodenoscopy (EGD); and
    b. Colonoscopy
4. For evaluation or reevaluation of suspected or known small bowel neoplasms.

B. Diagnosis of suspected Crohn's disease (regional enteritis) that meet the conditions under 1 and 2 below:

1. Two or more of the following symptoms and signs associated with Crohn's disease, such as:
    a. abdominal pain;
    b. diarrhea;
    c. fever;
    d. elevated white blood count;
    e. elevated erythrocyte sedimentation rate;
    f. documented weight loss;
    g. gastrointestinal bleeding with positive fecal occult blood test or blood loss visualized in stool

    And
2. One of the following test series outcomes

a. Upper GI with small bowel follow through does not reveal an obstruction or stricture (patients with a suspected fistula or stricture will need an UGI with small bowel follow through); or,
b. EGD and colonoscopy do not reveal the location of the pathology.

C. Suspected small bowel tumors including loco-regional carcinoid tumors of the small bowel with carcinoid syndrome.
D. Evaluation of celiac disease with a negative biopsy and positive serology or unable to undergo upper endoscopy.
E. For small bowel surveillance in Lynch syndrome, Familial Adenomatous Polyposis, Peutz-Jegher's syndrome and other inherited polyposis syndromes.
F. For evaluation of the esophagus after radio-frequency ablation of lesions in the esophagus
G. For re-evaluation of Crohn's or Celiac disease which remains symptomatic despite treatment, requested, or recommended by gastroenterology for medical necessity and where there is no suspected or confirmed gastrointestinal obstruction, stricture, or fistulae.
H. For screening or surveillance of esophageal varices in cirrhotic persons with significantly compromised liver function (i.e., Child-Pugh score of Class B or greater) or other situations where a standard upper endoscopy with sedation or anesthesia is contraindicated.

III. Contraindications for use

A. Absolute contraindications
1. Obstruction; and
2. Pregnancy

B. Relative contraindications
1. Fistulas; and
2. Intestinal strictures

IV. Exclusions

Capsule endoscopy is considered ***experimental/investigational and excluded from coverage*** for all other indications including but not limited to the following:

1. Screening colonoscopy;
2. Initial test for gastrointestinal bleeding;
3. Confirmation of lesions or pathology normally within the reach of upper (EGD) and lower (colonoscopy) endoscopies (lesions proximal to ligament of Treitz or distal to the ileum);
4. Hematemesis; and
5. Suspected Irritable Bowel Disease, Celiac Sprue, and malabsorption as initial testing

References

1. Cohen SA. Use of capsule endoscopy in diagnosis and management of pediatric patients, based on meta-analysis. - Clin Gastroenterol Hepatol Jun 2011; 9(6): 490-6.
2. Di Biase L Capsule endoscopy in examination of esophagus for lesions after radiofrequency catheter ablation: a potential tool to select patients with increased risk of complications. *J Cardiovsc Electrophysiol* Aug 2012; 21(8): 839-44.
3. Dionisio PM, Gurudu SR, Leighton JA, et al. Capsule endoscopy has a significantly higher diagnostic yield in patients with suspected and established small-bowel Crohn's disease: a meta-analysis. *Am J Gastroenterol* 2010; 105:1240-8
4. Freitas GP. Capsule endoscopy in clinical practice: four years of experience from a single center. *Arq Gastroenterol* Jul 2011; 48(3): 220-2.
5. Fukumoto A, Tanaka S, Shishido T, Takemura Y, Oka S, Chayama K. Comparison of detectability of small-bowel lesions between capsule endoscopy and double-balloon endoscopy for patients with suspected small-bowel disease. Gastrointestinal Endoscopy 2009; 69(4):857-65.
6. Gastineau S, et al. Contribution of capsule endoscopy to Peutz-Jeghers syndrome management in children. Digestive and Liver Disease 2012; 44(10):839-43.
7. Girelli CM. Small bowel capsule endoscopy performance in octogenarians: a case-control study. *J Gerontol* Jan 2011; 66(1): 68-73.
8. Gottumakkala, S Raju et al. American Gastroenterological Association (AGA) Institute Medical Position Statement on Obscure Gastrointestinal Bleeding, *Gastroenterology* Nov 2007 133(5), 1694-1696
9. Gunther U. Capsule endoscopy in small-bowel surveillance of patients with hereditary polyposis syndromes. *Int J Colorectal Dis* Nov 2010; 25(11): 1377-82.
10. Gupta A, A prospective study of MR Enterography versus capsule endoscopy for the surveillance of adult patients with Peutz-Jeghers syndrome. *Am J Roentgenol* Jul 2010; 195(1): 108-16.
11. Guturu P. Capsule endoscopy with PILLCAM ESO for detecting esophageal varices: a meta-analysis. *Minerva Gastroenterol Dietol* Mar 2011; 57(1): 1-11.
12. Kim HM. A pilot study of capsule endoscopy for the diagnosis of radiation enteritis. *Hepatogastroenterology* Mar 2011; 58(106): 459-64.
13. Kurien M, et al. Capsule endoscopy in adult celiac disease: a potential role in equivocal cases of celiac disease? Gastrointestinal Endoscopy 2013; 77(2):227-32.
14. Lee NM, Eisen GM. 10 years of capsule endoscopy: an update. *Expert Rev Gastroenterol Hepatol.* Aug 2010; 4(4):503-12.
15. Li B. Tumor recognition in wireless capsule endoscopy images using textural features and SVM-based feature selection. *IEEE Trans Inf Technol Biomed* May 2012; 16(3): 323-9.
16. Medicare Coverage Database “Wireless Capsule Endoscopy” LCD L35089, revised 3/08/2018. Primary Geographic Jurisdiction: Maryland. Coverage database accessed 08/23/2018.
17. Ohmiya N. Management of small-bowel polyps in Peutz-Jeghers syndrome by using enteroclysis, double-balloon enteroscopy, and videocapsule endoscopy. *Gastrointest Endosc* Dec 2010; 72(6): 1209-16.
18. Riccioni ME, Urgesi R, Cianci R et al. Negative capsule endoscopy in patients with obscure gastro-intestinal bleeding reliable: Recurrence of bleeding on long term follow up. *World J Gastroenterol* Jul

2013: 19(28): 4520-5.
19. Tennyson CA. The role of capsule endoscopy in patients with nonresponsive celiac disease. Gastrointestinal Endosc Dec 2011; 74(6): 1323-4.
20. Urgesi R., Cianci R., Bizzotto A., Costamagna G., Riccioni ME. Evaluation of gastric and small bowel transit times in celiac disease with the small bowel. Pillcam: a single centre study in a non-gluten-free diet adult Italian population with celiac disease. European Review for Medical and Pharmacological Sciences 2013; 17(9): 1167-73.
21. Yamada, A., Wataabe, H., Iwama, T., Obi, S., Omata, M., Koike, K., (2013, June). The prevalence of small intestinal polyps in patients with familial adenomatous polyposis: a prospective capsule endoscopy study. *Fam Cancer.* Accessed 10/7/2015. http://ww.ncbi.nlm.nih.gov/pubmed/23743563.
22. Effectiveness of Capsule Endoscopy Compared with Other Diagnostic Modalities in Patients with Small Bowel Crohn's Disease: A Meta-analysis by Choi M; Lim, S; Choi, MG; Shim, KN: Lee SH, Gut and Liver [Gut Liver], ISSN: 2005-1212, 2017 Jan 15: Vol.11 (1), pp. 62-72; publisher: Editorial office of Gut and Liver: PMID: 27728963. 8
23. Screening individuals' experiences of colonoscopy and colon capsule endoscopy; a mixed methods study. (Includes abstract) Thygesen, Marianne K.; Baatrup, Gunnar; Petersen, Christina; Qvist, Niels; Kroijer, Rasmus; Kobaek-Larsen, Morten; Acta Oncologica, 2019 Supplement; 58 S71-S76. 6p. (Article) ISSN: 0284-186X, Database: CINAHL with Full Text
24. Cave DR, Hakimian S, Patel K. Current Controversies Concerning Capsule Endoscopy. *Dig Dis Sci*. 2019;64(11):3040-3047. doi:10.1007/s10620-019-05791-4 https://pubmed.ncbi.nlm.nih.gov/31468267/
25. Zhang S, Sun T, Xie Y, et al. Clinical Efficiency and Safety of Magnetic-Controlled Capsule Endoscopy for Gastric Diseases in Aging Patients: Our Preliminary Experience. *Dig Dis Sci*. 2019;64(10):2911-2922. doi:10.1007/s10620-019-05631-5 https://link.springer.com/content/pdf/10.1007/s10620-019-05631-5.pdf
26. Le Berre C, Trang-Poisson C, Bourreille A. Small bowel capsule endoscopy and treat-to-target in Crohn's disease: A systematic review. *World J Gastroenterol*. 2019;25(31):4534-4554. doi:10.3748/wjg. v25.i31.4534 https://www.wjgnet.com/1007-9327/full/v25/i31/4534.htm
27. Wetwittayakhlang P; Wonglhow J; Netinatsunton N; Chamroonkul N; Piratvisuth T. Re-bleeding and its predictors after capsule endoscopy in patients with obscure gastrointestinal bleeding in long-term follow-up. (English). Abstract available. *BMC gastroenterology [BMC Gastroenterol],* ISSN: 1471-230X, 2019 Dec 16; Vol. 19 (1), pp. 216; Publisher: BioMed Central; PMID: 31842770, Database: MEDLINE PubMed
28. MacLeod, C., Wilson, P., & Watson, A. (2020). Colon capsule endoscopy: an innovative method for detecting colorectal pathology during the COVID-19 pandemic? *Colorectal disease: the official journal of the Association of Coloproctology of Great Britain and Ireland*, *22*(6), 621–624. https://doi.org/10.1111/codi.15134
29. Deding, U., Kaalby, L., Bøggild, H., Plantener, E., Wollesen, M. K., Kobaek-Larsen, M., Hansen, S. J., & Baatrup, G. (2020). Colon Capsule Endoscopy vs. CT Colonography Following Incomplete

Colonoscopy: A Systematic Review with Meta-Analysis. *Cancers*, *12*(11), 3367. https://doi.org/10.3390/cancers12113367

30. Blanco-Velasco, G., Palos-Cuellar, R., Domínguez-García, M. R., Solórzano-Pineda, O. M., Zamarripa-Mottú, R. A., Martínez-Camacho, C., González-Bautista, M. L., Contreras-Serratos, M. M., Murcio-Pérez, E., Blancas-Valencia, J. M., Jiménez-Ochoa, M. A., & Hernández-Mondragón, O. V. (2020). Utility of capsule endoscopy in the diagnosis of gastrointestinal graft-versus-host disease. Utilidad de la cápsula endoscópica en el diagnóstico de la enfermedad injerto contra huésped gastrointestinal. *Revista de gastroenterologia de Mexico*, S0375-0906(20)30086-0. Advance online publication. https://doi.org/10.1016/j.rgmx.2020.06.005
31. Innocenti, T., Dragoni, G., Roselli, J., Macrì, G., Mello, T., Milani, S., & Galli, A. (2021). Non-small-bowel lesions identification by capsule endoscopy: A single centre retrospective study. *Clinics and research in hepatology and gastroenterology*, *45*(1), 101409. https://doi.org/10.1016/j.clinre.2020.03.011
32. Hilmi, I., & Kobayashi, T. (2020). Capsule endoscopy in inflammatory bowel disease: when and how. *Intestinal research*, *18*(3), 265–274. https://doi.org/10.5217/ir.2019.09165
33. Marya, N. B., Jawaid, S., Foley, A., Han, S., Patel, K., Maranda, L., Kaufman, D., Bhattacharya, K., Marshall, C., Tennyson, J., & Cave, D. R. (2019). A randomized controlled trial comparing efficacy of early video capsule endoscopy with standard of care in the approach to non-hematemesis GI bleeding (with videos). *Gastrointestinal endoscopy*, *89*(1), 33–43. e4. https://doi.org/10.1016/j.gie.2018.06.016
34. Hayashi, Y. et al. A narrative review of recent progress and current perspectives on video capsule endoscopy. *Dig Med Res* 2021; 4:5 | http://dx.doi.org/10.21037/dmr https://dmr.amegroups.com/article/view/7169/html
35. Cohen, S. and Oliva, S. Capsule Endoscopy in Children. *Front. Pediatr.,* 13 August 2021. Sec. Pediatric Gastroenterology, Hepatology and Nutrition Volume 9 - 2021 | https://doi.org/10.3389/fped.2021.664722 https://www.frontiersin.org/articles/10.3389/fped.2021.664722/full
36. Leighton, Jonathan A. MD, FACG1; Brock, Andrew S. MD2; Semrad, Carol E. MD, FACG3; Hass, David J. MD, FACG4,5; Guda, Nalini M. MD, FACG6; Barkin, Jodie A. MD7; Eisen, Glenn M. MD, MPH8. Quality Indicators for Capsule Endoscopy and Deep Enteroscopy. *The American Journal of Gastroenterology* 117(11): p 1780-1796, November 2022. | DOI: 10.14309/ajg.0000000000001903 https://journals.lww.com/ajg/Fulltext/2022/11000/Quality_Indicators_for_Capsule_Endoscopy_and_Deep.20.aspx
37. MCG 28th edition. Copyright © 2024 MCG Health, LLC, Wireless Capsule Endoscopy A-0134; Accessed 02/27/2024
38. Kim, S. H., & Chun, H. J. (2021). Capsule Endoscopy: Pitfalls and approaches to overcome. Diagnostics, 11(10). https://doi.org/10.3390/diagnostics11101765
39. Stefania Chetcuti Zammit & Reena Sidhu (2021) Capsule endoscopy – Recent developments and future directions, Expert Review of Gastroenterology & Hepatology, 15:2, 127-137, https://doi.org/10.1080/17474124.2021.1840351
40. Levine, I., Hong, S., Bhakta, D. et al. Diagnostic yield of inpatient capsule endoscopy. BMC Gastroenterol 22, 236 (2022). https://doi.org/10.1186/s12876-022-02323-9

Approval History

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Effective June 01, 2016, state filing is no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

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10/21/2016	10/21/2016
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*The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Whenever possible, Medical Coverage Policies are evidence-based and may also include expert opinion. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.