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CT039-20A
Hartford, CT 06103

May 4, 2023

Ms. Terri Smith
Director, Life and Health Complaints
Maryland Insurance Administration
200 St. Paul Place
Suite 2700
Baltimore, MD 21202

Re: UnitedHealthcare's new prior authorization process for Gastrointestinal procedures

Dear Ms. Smith:

I am writing in response to your inquiry about UnitedHealthcare's new prior authorization process for Gastrointestinal procedures.

On March 1, 2023, UnitedHealthcare sent a communication to providers notifying them that, as of June 1, 2023, there would be certain codes for gastroenterology services that would require prior authorization. It is important to note that these new requirements do not apply to screening colonoscopies for preventive care or any other preventive services. Nor do they apply to procedures performed in an emergency room, urgent care center, observation unit, or inpatient setting.

To elaborate on what was explained in the communication, the new policies and prior authorization requirements are being implemented because multiple studies have shown overutilization or unnecessary use of non-screening (surveillance and diagnostic) colonoscopy, esophagogastroduodenoscopies (EGD), and capsule endoscopy procedures, which may expose our members to unnecessary medical risks and additional unnecessary out of pocket costs.[1] Moreover,

[1] *See, e.g.*, Cai, J., *et al*., *Concordance of Outpatient Esophagogastroduodenoscopy of the Upper Gastrointestinal Tract with Evidence-Based Guidelines,* 175 JAMA Internal Med. No. 9, pp. 1563-4 ("Results |We identified 550 EGDs that were performed in 549 patients …. Of the EGDs, 208 (37.8%) were discordant with the evidence-based guidelines."); Shaheen, N., *et al*., *Less Is More: A Minimalist Approach to Endoscopy*, 154 Gastroenterology, No. 7, pp. 1993-2003 (2018) ("Multiple studies have demonstrated overuse or inappropriate use of endoscopy, in a number of clinical settings. Best documented is the use of colonoscopy for colorectal cancer screening and surveillance. When judged against practice informed by evidence-based clinical guidelines, a large percentage of endoscopists both screen and survey more often than necessary."); Dong, J., *et al*., *Real-World compliance with the 2020 U.S. Multi-Society Task Force on Colorectal Cancer polypectomy surveillance guidelines: an observational study*, 97 Gastrointestinal Endoscopy, Issue 2, 350-356e.3 (Feb. 2023) ("Although colonoscopy is considered the criterion standard test in colorectal cancer (CRC) screening, overuse of colonoscopy reduces the cost-effectiveness of screening, increases the risk of procedural adverse events, and may divert resources from providing other

despite ample clinical evidence and recommendations from key specialty professional societies, according to published literature, provider adherence to current guidelines has been "mediocre."[2]

The risks of complications or adverse events from overutilization of gastroenterology procedures, which are invasive in nature, are potentially significant. For instance:

- The general estimate of adverse events for EGD is 1 - 2 per 1000. However, this may be an underestimation as not all adverse events happen immediately. One study found a 1.07% hospital visit rate over 14 days following the procedure.[3]
- Complications from colonoscopy such as GI bleeding, bowel perforation or cardiac events can result in hospitalization or emergency department visits within 30 days after a colonoscopy.[4]
- Risk for complications increases with age from 2% for age 55 - 59 years old to 4% for age 70 – 74 to 6.8% for those over age 75.[5]

This is why we are asking health care professionals to align with current evidence-based practices and guidance from gastroenterology-related medical societies to help ensure our members are receiving safe and clinically appropriate care.

UnitedHealthcare's new clinical policies are evidence-based and were developed from and are supported by current, published peer-reviewed clinical research.[6] These policies are consistent with the

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medical care."); De Jong, J., *et al*., *Prevention of overuse: A view on upper gastrointestinal endoscopy*, 25 World J. Gastroenterology, Vol. 2, 178–89 (2019) (noting that up to 56% of diagnostic upper endoscopy procedures are not according to clinical guidelines and this inappropriate use is "a major source of unnecessary cost, risk of complications, and are associated with reduced diagnostic yield"); Rubenstein, J., *et al*., *Overuse of Repeat Upper Endoscopy in the Veteran's Health Admin.: A Retrospective Analysis*, 112 Am. J. Gastroenterology, Issue 11, pp. 1678-85 (2017) ("Americans undergo ∼7 million [EGDs] annually, and one-third of Medicare beneficiaries undergo a repeat EGD within 3 years. As many as 43% of these repeat EGDs are inappropriate."); Saini, S., *et al*., *Utilization of upper endoscopy for surveillance of gastric ulcers in the U.S.*, 103 Am. J. Gastroenterology Issue 8, at pp. 1920-5 (2008) ("In contrast to guideline recommendations, approximately 25% of ambulatory patients diagnosed with GUs underwent surveillance EGD within 3 months. Notably, patients at low risk for gastric cancer, including young patients, those with small index ulcers, and those with antral ulcers, underwent surveillance at higher than expected rates, which suggests overuse of surveillance EGD.").

[2] Dong, *et al*., *supra*, note 1 ("Although multiple medical societies have released guidelines on colonoscopy surveillance intervals, compliance with these guidelines has been mediocre".); *see also* Shaheen, *et al*., *supra*, note 1 ("When judged against practice informed by evidence-based clinical guidelines, a large percentage of endoscopists both screen and survey more often than necessary."); Hennessey, M., et al., *Low compliance with USMSTF on colorectal cancer postpolypectomy guidelines*, 97 Gastrointestinal Endoscopy J., Issue 2, pp. 357-6 (Feb. 2023) (noting main findings from study by Dong, *et al*., *supra* note 1, "demonstrate low compliance among endoscopists for surveillance recommendations" and "the low adherence may not be explained simply by a lack of guideline awareness.").

[3] Leffler D., *et al*., *The Incidence and Cost of Unexpected Hospital Use After Scheduled Outpatient Endoscopy*, 17 Arch Intern Med. Vol. 19, pp. 1752-7 (2010).

[4] Causado-Cho, N., *et.al*., *Association between age and complications after outpatient colonoscopy*, 3 JAMA Network Open, Issue 6, at e208958 pp. 1-13 (June 25, 2020).

[5] *Id.* at 6; *see also* Kim, H., *et. al*., *Gastrointestional and Nongastrointestional Complications of Esophagogastroduodenoscopy and Colonoscopy in the Real World: A Nationwide Standard Cohort Using the Common Data Model Database*, 17 Gut and Liver, No. 2 (2023) ("In our study, the complication rates of GI bleeding, CVA, AMI, CHF, and death were significantly higher in the elderly group.").

[6] Each policy contains references to dozens of sources in literature on which they were based, including guidelines from the three professional societies mentioned above. UnitedHealthcare Esophagogastroduodenoscopy (EGD)

clinical criteria supporting Medicare guidelines,[7] with National Institute for Health and Care Excellence (NICE) Guidance,[8] and with recommendations from key specialty professional societies such as American Gastroenterological Association, the American College of Gastroenterology and the American Society of Gastrointestinal Endoscopy.[9] We have met with and intend to continue to engage in ongoing discussions with these three professional societies to ensure they understand the program, and we remain open to reviewing their feedback and suggestions.

While clinically it was important for us to implement a mechanism to help address the overutilization of gastroenterology procedures, we also recognize the challenges providers face with prior authorization programs. We have made extensive efforts to align this program with the American Medical Association's "Prior Authorization and Utilization Management Reform Principles"[10] to improve the provider and member experience. Examples of those efforts as it relates to this program include:

- Multiple upper and lower GI endoscopy procedures can be submitted on the same request.
- Decisions for a standard request are typically made within 2 business days of receipt of all required clinical information.
- Decisions for an expedited request are typically made within 3 hours during the business day of receipt of all required clinical information.

Guidelines, pp. 18-20 (Effective June 1, 2023); UnitedHealthcare Capsule Endoscopy Guidelines, pp. 9-10 (Effective June 1, 2023); UnitedHealthcare Colonoscopy Guidelines, pp. 15-17 (Effective June 1, 2023).

[7] *Compare* Colon Capsule Endoscopy (CCE), Local Coverage Determination (LCD) L38807 (Effective: March 28, 2021) (Colon Capsule Endoscopies are considered medically necessary as a primary procedure for individuals who have a positive fecal occult blood test; a positive multitarget stool DNA test; or have other evidence of lower GI bleeding and are hemodynamically stable) *with* UnitedHealthcare Capsule Endoscopy Guidelines, p. 6 (Effective June 1, 2023) (same); *see also* Centers for Medicare & Medicaid Services, Quality ID #185: colonoscopy interval for patients with a history of adenomatous polyps - avoidance of inappropriate use (December, 2021) ("Patients with only 1 or 2 small (<1 cm) tubular adenomas with only low-grade dysplasia should have their next follow up colonoscopy in 7-10 years ….") *compare with* UnitedHealthcare Colonoscopy Guidelines (Effective June 1, 2023), p. 3 ("Surveillance after Polypectomy … 1-2 tubular adenomas < 10 mm: 7-10 years"); *see also* Colon Capsule Endoscopy (CCE), Local Coverage Determination (LCD) L38824, *compare with* UnitedHealthcare Capsule Endoscopy Guidelines, p. 6 (Effective June 1, 2023).

[8] *E.g.*, *Compare* NICE, Colorectal cancer prevention: colonoscopic surveillance in adults with ulcerative colitis, Crohn's disease or adenomas, Clinical Guideline [CG118] (March 23, 2011) (baseline surveillance colonoscopy should be offered to patients with inflammatory bowel disease (IBD) with ulcerative colitis (UC) whose symptoms started 10 years ago with surveillance colonoscopies every 3-5 years for moderate to low risk of cancer and yearly for high risk of cancer) *with* UnitedHealthcare Colonoscopy Guidelines (Effective June 1, 2023), p. 7 (baseline surveillance colonoscopy for IBD with UC at 8 years after symptom onset with surveillance colonoscopies every 1-3 years for average risk of cancer and yearly for high risk); *see also* NICE, Gastroesophageal reflux disease and dyspepsia in adults: investigation and management [CG184], (October 18, 2019) (recommending full-dose PPI for 8 weeks to heal severe esophagitis) *compare with* UnitedHealthcare Esophagogastroduodenoscopy Guidelines (Effective June 1, 2023), p. 6 (EGD may be indicated for GERD after an 8 week trial of PPIs).

[9] Yang, J., *et. al*., *American Society for Gastrointestinal Endoscopy Guideline on the role of endoscopy in familial adenomatous polyposis syndromes*, 91 Gastrointestinal Endoscopy, No. 5, pp. 963-82 (2020); Ford, A., *et. al*., *American College of Gastroenterology monograph on the management of Irritable Bowel Syndrome and chronic idiopathic constipation*. 113 Am J Gastroenterology, Vol. 1, pp. 1-18 (2018); Gupta, S., *et. al., AGA clinical practice guidelines on management of gastric intestinal metaplasia*. 158 Gastroenterology, Vol 3, pp. 693-702 (2019).

[10] The "Prior Authorization and Utilization Management Reform Principles" document is available at: Prior Authorization and Utilization | AMA (ama-assn.org).

- The initial gastroenterology endoscopy clinical reviews and peer to peer discussions will be performed by board certified gastroenterologists.
- All clinical criteria used in making medical necessity determinations for these services are publicly available on our websites.

This program is part of our efforts to ensure prior authorization programs are implemented for the procedures that can have a material impact on member safety and quality of care when performed too often or inappropriately.

Sincerely,

Robert D. Morrow Jr.
VP Regulatory Affairs/Deputy General Counsel