Clinical Review Criteria
Defecography for Diagnosing Defecation Disorders

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Criteria
For Medicare Members

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<tr>
<td>CMS Coverage Manuals</td>
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<td>National Coverage Determinations (NCD)</td>
<td>Magnetic Resonance Imaging (220.2)</td>
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<td>Local Coverage Determinations (LCD)</td>
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For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
Defecation is a highly complex physiologic process that requires normal colonic transit, ano-rectal sensation, expulsion force, and coordinated function of the pelvic floor for successful evacuation. A disturbance at any level of this process can lead to a defecation disorder (DD) (Maccioni 2013). DDs encompass a variety of clinical conditions including obstructed defecation syndrome, rectocele, rectal intussusception, rectal prolapse and enterocoele. Patients typically report symptoms such as excessive straining, sensation of blockage, and a feeling of incomplete evacuation. Some patients even report a need to use digital maneuvers to defecate, and frequent use of enemas or suppositories. While the true prevalence of DD is unknown, the symptom of constipation is extremely common in the United States with a reported 5.7 million constipation-related physician visits in 2006 alone. While not life threatening, DDs can cause a considerable amount of morbidity and, in some cases, have devastating impacts on quality of life.
In most cases, diagnosis of DDs can be established accurately based on physical examination and detailed history. However, symptoms can be nonspecific and overlapping. While there is no gold standard for pinpointing the cause of DD, current practice guidelines from national bodies recommend physiological testing such as ano-rectal manometry (ARM) and rectal balloon expulsion tests (BET). In the event of equivocal results, however, direct visualization of the pelvic floor and lower bowel may be necessary (AGA 2013; Wald, Bharucha et al. 2014). Defecography, first described in 1952 by Wallden, was initially developed for the evaluation of outlet obstruction (Wallden 1952). Since then, however, defecography has evolved to not only detect structural abnormalities, but also to assess functional parameters. Although it has been recognized as a useful diagnostic technique, methods and interpretation of defecography have not yet been standardized. Conventionally, the technique involves placement of a contrast medium into the rectum, similar to the consistency of stool, and laterally imaging activity throughout defecation using fluoroscopy. Alternatively, defecography can also be performed in the supine or upright position with magnetic resonance imaging (MRI). In any case, interpretation of the imaging focuses on the anal rectal angle (ARA) at rest and during straining providing an indirect measurement of the function of the puborectalis muscle. Additionally, imaging can provide information about perineal descent, anal diameter, indentation of the puborectalis, and the amount of rectal and rectocele emptying.
Defecography for Diagnosing Defecation Disorders

Medical Technology Assessment Committee (MTAC)

10/20/2014: MTAC REVIEW

Evidence Conclusion: A 2011 study conducted in France by Vitton and colleagues compared the accuracy of both MRI defecography and dynamic anal endosonography (DAE) using conventional defecography as the gold standard. The study involved 56 female patients with a history of dyschezia. Patients received each procedure randomly over a one-month period. Using conventional defecography as the criterion standard, the investigators calculated a range of sensitivities and specificities for detecting rectoceles, perineal descent, and enterocele. For both DAE and MRI, the sensitivities were highest in detecting rectoceles at 73.5% and 81.6%, respectively. For detecting perineal descent and enterocele the sensitivities were 61% and 58.3% for DAE and 46.3% and 66.7% for MRI. Specificities were 100% in both DAE and MRI for identifying enteroceles. The specificities were lower for perineal descent 73.3% (DAE) and 86.7% (MRI) and rectoceles 85.7% (DAE) and 85.7% (MRI). Although MRI defecography performed better than DAE no significant differences were observed between the diagnostic techniques and both correlated well with conventional defecography under the Youden index and the Yule correlation coefficient. Regardless, conventional defecography is an imperfect gold standard limiting the value of these results (Vitton, Vignally et al. 2011). Foti and colleagues also prospectively compared conventional and MRI defecography. In this study, 19 consecutive patients with outlet obstruction syndrome (OOS) underwent both conventional and MRI defecography. With the overall aim to develop a protocol for MRI defecography the comparisons between the two techniques showed no significant differences in sphincter hypotonia, dyssynergia, rectocele and rectal prolapse. Significant differences were, however, seen in descending perineum. Ultimately, the authors concluded that while MR imaging provides morphological and functional study of pelvic floor structures it cannot replace CD and may offer benefit if offered as a complementary tool to CD in evaluating OOSs (Foti, Farina et al. 2013). In a meta-analysis that sought to estimate the prevalence of abnormal findings associated with dyssynergic defecation across testing modalities, 79 studies including 7,581 patients were pooled and analyzed. The overall prevalence of any single abnormal dynamic pelvic floor test ranged from 14.9% to 52.9% with a median of 37.2%. The investigators note that the prevalence of abnormal tests tended to be lower in defecographic studies accounting for the lower end of this range. In addition to identifying a high prevalence of dyssynergic defecation in patients with chronic constipation, the investigators suggest that the lower prevalence of abnormalities found with defecography supports the use of ARM and BET for initial evaluation (Videlock, Lembo et al. 2013). None of the selected studies overtly assessed the safety and harms of defecography however, theoretically, the harms of conventional defecography include all those that we know to be associated with radiation exposure. In the study by Vitton and colleagues, patient tolerance and preference for assessment procedures was examined using a visual analogue scale. Tolerance was rated “high” or “very high” more frequently in the MRI defecography group (44.9%) than in the conventional defecography group (36.7%), although this difference was not significantly significant (P=0.9). This partiality was mirrored in a 2012 study, by Pilkington and colleagues, assessing patient acceptance of conventional and MRI defecography. In this study, the investigators administered questionnaires to 42 patients undergoing defecography (of these patients 25 patients completed for both conventional and MRI defecography). Over half of patients (62%) who underwent both procedures identified MRI proctography as the preferred technique. When asked why, all of these patients cited ‘less embarrassing’ as the reason for preference (Pilkington, Nugent et al. 2012). The clinical utility of diagnostic tests for constipation in adults was examined in a 2005 systematic review by Rao and colleagues. The investigators were able to identify ten case series related to the use of defecography. Although the results of the included studies did not allow for meta-analysis, the investigators found the results of the included studies to be conflicting citing significant overlap of findings between patients and healthy controls and poor correlation of symptoms with defecographic findings. Ultimately, defecography was recognized as a useful source of information regarding the anatomical and functional changes of the anorectum but concluded that the technique should only be regarded as an adjunct to clinical assessment and not relied upon as a sole diagnostic test. This study was not critically appraised due to lack of meta-analysis (Rao, Ozturk et al. 2005). Overall, the literature should be interpreted with caution. Beyond the heterogeneous nature of the populations across the literature, an inherent difficulty of evaluating the accuracy of defecography is that there is the lack of a true gold standard. To add to this, diagnostic criteria are continually changing inhibiting the ability to establish a standard technique or interpretation. Without adequately defined ranges for quantified measures and parameters interpretation relies on opinion rather than objective findings. Beyond that, no studies have been able to demonstrate that defecography contributes to improved diagnosis and more appropriate patient management.

Conclusions: There is insufficient evidence to conclude that defecography is accurate in the evaluation of DD. There is insufficient evidence to conclude that defecography is not harmful to patients. There is insufficient evidence to conclude that defecography contributes to improved diagnosis of DD. There is insufficient evidence to conclude that defecography leads to more appropriate management of patients with DD.

Articles: The literature search revealed just over 200 publications addressing defecography, the majority of which were continuing medical educational materials, manuscripts or editorials. The remainder was comprised of small

The use of Defecography for Diagnosing Defecation Disorders does not meet the Kaiser Permanente Medical Diagnostic Test Assessment Criteria.

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MPC Medical Policy Committee

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**Codes**

CPT: 72195, 72196, 72197 with dx codes K59.00-K59.09, K59.4, K62.89