Wireless Capsule for the Evaluation of Suspected Gastric and Intestinal Motility Disorders

Policy # 00470
Original Effective Date: 06/17/2015
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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Wireless Capsule Endoscopy for Gastrointestinal (GI) Disorders is addressed separately in medical policy 00137.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers a wireless capsule (e.g., SmartPill Motility Testing System) for evaluation of all conditions including, but not limited to the following to be **investigational:***

- Suspected gastric motility disorders (e.g., gastroparesis); **or**
- Suspected intestinal motility disorders (e.g., constipation).

Background/Overview

Gastroparesis is a "syndrome of objectively delayed gastric emptying in the absence of mechanical obstruction and cardinal symptoms…" The symptoms include "early satiety, postprandial fullness, nausea, vomiting, bloating, and upper abdominal pain." Similar symptoms can be present with other conditions such as peptic ulcer and functional dyspepsia and thus the combination of symptoms and documentation of delayed gastric emptying is needed to confirm the diagnosis of gastroparesis. Gastric emptying scintigraphy of a solid-phase meal is considered the standard method of identifying delayed gastric emptying and gastric retention at 4 hours is the most reliable parameter with which to quantify gastric emptying. Breath testing, such as those that use 13 C-octanoate or 13 C-spirulina, are a potential alternative to gastric emptying scintigraphy. However, an American College of Gastroenterology 2013 clinical guideline states that breath tests require additional validation (Camilleri, 2013).

Another potential option for evaluation of suspected gastroparesis is use of a WMC. A WMC device, known as the SmartPill Motility Testing System (Medtronic), has been cleared for marketing by the U.S. Food and Drug Administration (FDA). According to the FDA 510(k) documents, the SmartPill is indicated for use in evaluating individuals with suspected delayed gastric emptying (gastroparesis) as well as for the evaluation of colonic transit in those with chronic constipation. The SmartPill measures pH, pressure and temperature throughout the gastrointestinal tract. This data is then transmitted from the capsule via radio signal to an individually-worn data receiver and downloaded to a computer in the physician's office for analysis and review. The recorded physiological measurements are used to determine GET, total transit time, and combined small-large bowel transit time. In addition, pressure contraction patterns from the antrum and duodenum are used to calculate motility indices.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Wireless Motility Capsule for the Evaluation of Suspected Gastroparesis

An early study evaluating WMC was published by Kuo and colleagues in 2008. The study enrolled 87 healthy subjects and 61 individuals with known gastroparesis. Participants simultaneously ingested the wireless capsule and a radiolabeled meal, permitting a head-to-head comparison. The investigators did not indicate whether outcomes were interpreted in a blinded fashion. At 4 hours, the correlation between the two techniques was 0.73, which exceeded the prespecified target correlation. In a secondary analysis of data from 100 study participants, reported by Sarosiek and colleagues (2010), gastric emptying time (GET), colon transit time (CTT) and whole gut transit times (WGTT) but not small bowel transit time (SBTT) were noted to be longer in gastroparetics than in healthy controls. This study was limited in that it did not include individuals with suspected gastroparesis, the population of interest.

A 2013 comparative effectiveness review by the Agency for Healthcare Research and Quality (AHRQ) identified seven studies comparing WMC and gastric emptying scintigraphy (GES) for

diagnosing gastroparesis. Although the AHRQ report found that the diagnostic accuracy of WMC and GES were similar, the strength of evidence was determined to be low which indicated "low confidence that the evidence reflects the true effect". The main limitations contributing to the low strength of the evidence were that participant eligibility criteria and criteria for positive test findings were not clearly pre-specified. Moreover, most studies had limited durations of follow-up.

Hasler and colleagues (2017) compared WMC and GES in individuals with suspected gastroparesis, but did not report diagnostic accuracy or the impact on management decisions or health outcomes. In the study, 209 individuals with gastroparesis symptoms for at least 12 weeks with no evidence of organic disease underwent WMC and GES on different days. Individuals ceased taking medications prior to WMC testing. Blinding was not discussed. The overall agreement between GET and delayed 4-hour scintigraphic retention was 52.8% (kappa, 0.12). Agreement between GET and 2-hour scintigraphic retention was 58.7% (kappa, 0.16). The study investigators noted that device agreement was lower than that in the earlier study by Kuo and colleagues (2008), discussed above, and hypothesized that this difference may be due in part to the tests being performed on separate days in the current investigation whereas they were done on the same day in the Kuo study.

Several studies have compared simultaneous WMC and GES in individuals with suspected gastroparesis. In 2019, Lee and colleagues reported on delayed gastric emptying time in 167 individuals with gastroparesis who were assessed simultaneously by WMC and GES. Delayed gastric emptying by WMC was defined as more than 5 hours before passage of the capsule into the duodenum and delayed emptying by GES was defined as at least 10% meal retention at 4 hours. Delayed gastric emptying time by WMC occurred in 53 individuals (34.6%) and delayed gastric emptying by GES occurred in 39 individuals (24.5%). There was an overall device agreement between WMC and GES of 75.7%. Severely delayed gastric emptying was identified in 21 individuals (13.8%) by WMC and 11 individuals (7%) with GES. Agreement between WMC and GES for severe delayed gastric emptying was 38%. Significantly higher proportions of individuals with delayed and severely delayed emptying were identified by WMC.

In 2020, Sangnes and colleagues reported on 72 individuals with diabetes mellitus and suspected gastroparesis. The correlation between WMC and 4-hour GES was r=0.74 ($p<0.001$). At a cutoff of 300 minutes for gastric emptying time with WMC, the sensitivity compared with GES was 0.92 (95% confidence interval [CI], 0.74 to 0.99) and the specificity was 0.73 (95% CI, 0.57 to 0.86). The investigators found that the optimal cutoff for WMC was 385 minutes, for which the sensitivity was

92% (95% CI, 0.74 to 0.99) and the specificity was 0.83 (95% CI, 0.68 to 0.93). Although they included the population of interest, the Lee and Sangnes studies did not address the impact of diagnosis by WMC and GES on patient management or health outcomes.

Wireless Motility Capsule for the Evaluation of Suspected Chronic Constipation

Chronic constipation may be associated with a prolonged CTT or WGTT, both of which are typically measured using radiopaque markers (ROM). Validation of the wireless motility capsule to evaluate CTT or WGTT requires directly comparative studies with conventional ROM and blinded interpretation of results. In addition, the diagnosis of chronic constipation is based predominantly on clinical symptoms; therefore, studies should ideally document how measurements of transit times contribute to management of the condition (i.e., clinical utility).

A study by Camilleri and colleagues (2010) compared the wireless motility capsule to ROM measurements of colon transit. Of the 208 subjects recruited 180 individuals with self-reported symptoms of constipation were enrolled in the multicenter trial. The study participants ingested both the wireless motility capsule and ROM. After exclusions and missing data, the assessment of CTT was based on comparisons between WMC and ROM in 157 subjects, and comparison between small and large bowel transit time (SLBTT) by WMC and ROM in 154 subjects. Study results indicated that 59 of 157 subjects had delayed ROM colon transit. Overall device agreement was reported as 86%. There were correlations reported between ROM and WMC transit and between ROM and combined SLBTT. Estimates of CTT and SLBTT were calculated by a team reported as being blinded to the ROM transit results. Adverse events reported during the trial included the inability of 2 subjects to swallow the wireless motility capsule and 1 case each of abdominal cramping, nausea and loose or soft stools recorded as possibly related to the wireless motility capsule. The authors noted potential pitfalls of using all capsules to measure gut transit, including: "technical failures, inability to swallow the capsule, the potential for non-passage of or intestinal obstruction by the capsule in stenosing gut disorders, and greater cost relative to the ROM transit method."

A smaller study by Rao and colleagues (2009) compared transit times in both constipated (n=78) and healthy subjects (n=87) measured simultaneously with the WMC and ROM. The WMC estimated the SBTT based on pH changes as the capsule entered the duodenum (increase in pH) and then passed into the cecum (decrease in pH). The CTT was based on the time interval between entry into the cecum and the capsule exit from the body. Serial plain abdominal films were used to assess the movement of ROM. Correlation of the wireless motility capsule's colonic transit with ROMs

expelled on day 2/day 5 was r=0.74/r=0.69 in the constipated subjects, and r=0.70/r=0.40 in the control group, respectively. This study did not report whether or not the results were interpreted in a blinded fashion, and there was no discussion of how the diagnostic information was used in the management of the condition.

A 2013 comparative effectiveness review by the AHRQ identified five studies comparing WMC and ROM for diagnosing slow-transit constipation. Although the AHRQ report found that the diagnostic accuracy of WMC and ROM were similar, the strength of evidence (SOE) was determined to be low which indicated "low confidence that the evidence reflects the true effect". The determination of low SOE was due to several factors including the retrospective nature of the studies, uncertainty that the studies included the appropriate spectrum of participants, limited follow-up duration of most studies and unclear blinding of outcomes.

Wireless Motility Capsule for the Evaluation of Suspected Upper and Lower Gastrointestinal (GI) Motility Disorders

Several retrospective studies have been published. Rao and colleagues (2011a) evaluated the WMC in 86 individuals with suspected upper and lower gastrointestinal dysmotility. To be eligible, subjects needed to have symptoms of dysmotility (abdominal pain, nausea, vomiting, bloating, fullness after meals, constipation, straining, or feeling of incomplete evacuation) and normal endoscopic/radiologic evaluations. The diagnostic utility of the WMC was retrospectively assessed by examining device agreement and new information compared with conventional motility tests. Study subjects were classified into two subgroups on the basis of major symptom(s): lower GI (n=50) and upper GI (n=36). Clinical suspicion was confirmed in 52% and 66% of study subjects, respectively, and the authors stated there was good device agreement between the wireless motility capsule and conventional tests in 76% and 81% in the lower GI and upper GI groups, respectively. There was new diagnostic information with the wireless motility test in 53% of the lower GI (p=0.006) and 47% of the upper GI group (p=0.001). The wireless motility capsule detected generalized motility disorder in 44 (51%) subjects and influenced management in 30% of lower GI and 88% of upper GI subjects. Study limitations noted by the authors included potential bias of a retrospective study, the inclusion of subjects with more severe symptoms than are typically seen at a tertiary care center, and the tests were not carried out simultaneously which could result in discrepancy between the test results.

Kuo and colleagues (2011) evaluated the WMC in a retrospective study of 83 subjects with suspected gastroparesis, intestinal dysmotility, or slow transit constipation. Databases at two referral centers for gastrointestinal motility were accessed. Wireless motility capsule transits were analyzed and isolated regional delays were observed in 32% (9% stomach, 5% small bowel, 18% colon). Transits were normal in 32% and showed generalized delays in 35%. Symptom profiles were similar with normal transit, isolated delayed gastric, small intestinal and colonic transit, and generalized delay. Compared to conventional tests, WMC showed discordance in 38% and provided new diagnoses in 53%. Wireless motility testing reportedly influenced clinical management in 65 subjects (67%) (new medications 60%; modified nutritional regimens 14%; surgical referrals 6%) and eliminated needs for testing not already done including gastric scintigraphy (17%), small bowel barium transit (54%), and radiopaque colon marker tests (68%). A limitation of this study was that all subjects were from two academic centers specializing in managing severe dysmotility syndromes and would therefore differ from a representative community sample. Also of note, this retrospective investigation involved analyses of preexisting databases and data recording was not standardized, therefore reporting of a lack of a specific symptom or test result may not be the equivalent of symptom absence or non-performance of the test.

Arora and colleagues (2015) performed a single center retrospective chart review of 161 individuals who underwent wireless motility capsule testing. Wireless motility capsule testing was abnormal in 109 (67.7%) subjects. From the abnormal cases, 17 (15.6%) individuals had isolated delayed gastric emptying, 13 (11.9%) had isolated delayed small bowel transit, and 25 (22.9%) had isolated delayed large bowel transit. Multiregional (upper and lower) dysmotility was diagnosed in 54 (49.5%) cases. Of note, the presence or absence of various individually-reported symptoms by history did not predict an abnormal study. The authors concluded that "wireless motility capsule can be a useful diagnostic test in patients with suspected multiregional GI dysmotility." However, they also reported that a limitation of the study was that that they "did not attempt to assess if the results of the wireless motility capsule study changed the patients' outcome or management as the information needed was difficult to obtain in our settings and may be unreliable."

A retrospective chart review of 100 people with diabetes who had undergone wireless motility capsule testing at a single institution between the years 2010 to 2015 was performed by Rouphael and colleagues (2017). Of the original 103 subjects, 3 were excluded due to either a retained capsule (n=1) or missing data secondary to device failure (n=2). A total of 72% of subjects had abnormal wireless motility capsule testing, of which 40% (n=29) had multiregional dysmotility with 6.9%

(n=5) having delayed transit in all three GI tract segments. Information related to subsequent clinical management post testing was available for 47 subjects. The remaining 53 subjects were excluded from the analysis due to loss to follow-up or incomplete information related to treatment change or response to therapy. Of the 47 subjects, wireless motility capsule testing was abnormal in 70% (n=33) and treatment changes were made in 73% (n=24) of those with gut dysmotility. Limitations of this study included the retrospective nature of the analysis and small sample size.

Rodriguez and colleagues (2021) reported on a prospective series in 57 children age 8 to 18 years who underwent WMC evaluation of upper or lower GI symptoms. A total of 34 individuals also underwent a nuclear medicine gastric emptying study (NMGET) and 21 underwent a colonic radiopaque marker (CROM) transit study. The overall agreement between WMC and NMGET tests was 70%. In 8 individuals, there was an abnormal gastric residency time (GRT) with WMC and a normal NMGET, and GRT was normal in 2 individuals who had an abnormal NMGET. There was an overall agreement of 81% between WMC and CROM studies. A total of 4 individuals had an abnormal CROM study and a normal colonic transit time with WMC, and 1 individual had an abnormal colonic transit time with WMC and a normal CROM. Capsule prolonged retention (beyond 5 days) occurred in 9 individuals; at 2 weeks after the study, all of the capsules had been expelled. The study did not evaluate the ability of the WMC to predict health outcomes.

Other Considerations

A position paper of the American and European Neurogastroenterology and Motility Societies (Rao, 2011b), reviewed diagnostic tools used to assess regional or WGTT including the wireless motility capsule. The paper recommended the wireless motility capsule for the following:

- Assessment of gastric emptying and regional and WGTT in individuals with suspected gastroparesis and symptoms of upper GI dysmotility
- To facilitate detection of small bowel dysfunction in subjects with a more generalized GI motility disorder
- Assessment of CTT in subjects with constipation and those with suspected colonic disorders

Confounding issues or disadvantages involving the wireless motility capsule reported in the position paper included:

- Requires ingestion of a large capsule and wearing/returning a data receiver for up to five days if WGTT is being assessed

- Risk of capsule retention (20/2000 cases [0.33%] as of January 2010) which required endoscopic removal in two cases
- Use is contraindicated in those with pseudo-obstruction, ileus and gastric bezoar
- SBTT is not possible in some subjects, as pH landmarks cannot be accurately identified
- Requires physician training for interpretation, and device failure has been reported
- Has not yet been tested for colonic responsiveness to pharmacological agents

The American Gastroenterological Association (AGA) clinical practice guideline on management of medically refractory gastroparesis (Lacy, 2022) does not specifically have any best practice recommendations on use of wireless motility capsule. Their best practice advice includes the following: "clinicians should verify appropriate methodology of the gastric emptying study to ensure an accurate diagnosis of delayed gastric emptying", and "clinicians should classify patients with gastroparesis into mild, moderate, or severe based on symptoms and the results of a properly performed gastric emptying study".

Regarding the wireless motility capsule, the discussion in the guideline states:

> Because the wireless motility capsule, an inanimate object, identifies the phase III activity front of the migrating motor complex rather than overall gastric emptying, a meal-based test provides better physiological assessment of gastric emptying and is thus recommended as the first-line test of gastric emptying over the wireless motility capsule.

The recommendations made by professional societies regarding the wireless motility capsule are limited because there is insufficient supporting evidence to fully establish the clinical utility or accuracy of the SmartPill. In addition, significant confounding issues or disadvantages of the device have been reported.

Conclusion

Studies evaluating the usefulness of wireless motility capsule testing in suspected gastric motor disorders have been limited by study design limitations and some studies have small sample sizes. Larger well-designed studies are needed that compare results with use of this device (using an established protocol and cutoff values) with the current standard test. Evaluation of cases with discordant results would be of particular value. Ideally, these studies should be linked to therapeutic

decisions and to meaningful clinical outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information/Definitions

Gastric Emptying Scintigraphy (GES): A type of test which uses a radio-labeled meal to measure gastric emptying.

Gastroparesis: A condition where there is delayed gastric emptying and characteristic gastrointestinal symptoms.

References

Peer Reviewed Publications:

1. Arora Z, Parungao JM, Lopez R, et al. Clinical utility of wireless motility capsule in patients with suspected multiregional gastrointestinal dysmotility. Dig Dis Sci. 2015; 60(5):1350-1357.
2. Camilleri M, Thorne NK, Ringel Y, et al. Wireless pH-motility capsule for colonic transit: prospective comparison with radiopaque markers in chronic constipation. Neurogastroenterol Motil. 2010; 22(8):874-882, e233.
3. Hasler WL, May KP, Wilson LA, et al. Relating gastric scintigraphy and symptoms to mobility capsule transit and pressure findings in suspected gastroparesis. Neurogastroenterol Motil. 2018; 30(2): 1-12.
4. Hasler WL. The use of SmartPill for gastric monitoring. Expert Rev Gastroenterol Hepatol. 2014; 8(6):587-600.
5. Hasler WL, Coleski R, Chey WD, et al. Differences in intragastric pH in diabetic vs. idiopathic gastroparesis: relation to degree of gastric retention. Am J Physiol Gastrointest Liver Physiol. 2008; 294(6):G1384-1391.
6. Kuo B, Maneerattanaporn M, Lee AA, et al. Generalized transit delay on wireless motility capsule testing in patients with clinical suspicion of gastroparesis, small intestinal dysmotility, or slow transit constipation. Dig Dis Sci. 2011; 56(10):2928-2938.
7. Kuo B, McCallum RW, Koch KL, et al. Comparison of gastric emptying of a nondigestible capsule to a radio-labelled meal in healthy and gastroparetic subjects. Aliment Pharmacol Ther. 2008; 27(2):186-196.

8. Lee AA, Rao S, Nguyen LA et al. Validation of diagnostic and performance characteristics of the wireless motility capsule in patients with suspected gastroparesis. Clin Gastroenterol Hepatol. 2019; 17(9):1770-1779.
9. Parkman HP. Assessment of gastric emptying and small-bowel motility: scintigraphy, breath tests, manometry, and SmartPill. Gastrointest Endosc Clin N Am. 2009; 19(1):49-55, vi.
10. Rao SS, Kuo B, McCallum RW, et al. Investigation of colonic and whole-gut transit with wireless motility capsule and radiopaque markers in constipation. Clin Gastroenterol Hepatol. 2009; 7(5):537-544.
11. Rao SS, Mysore K, Attaluri A, Valestin J. Diagnostic utility of wireless motility capsule in gastrointestinal dysmotility. J Clin Gastroenterol. 2011a; 45(8):684-690.
12. Rodriguez L, Heinz N, Colliard K et al. Diagnostic and clinical utility of the wireless motility capsule in children: A study in patients with functional gastrointestinal disorders. Neurogastroenterol Motil. 2021; 33(4):e14032.
13. Rouphael C, Arora Z, Thota PN, et al. Role of wireless motility capsule in the assessment and management of gastrointestinal dysmotility in patients with diabetes mellitus. Neurogastroenterol Motil. 2017; 29 (9).
14. Sangnes DA, Søfteland E, Bekkelund M et al. Wireless motility capsule compared with scintigraphy in the assessment of diabetic gastroparesis. Neurogastroenterol Motil. 2020; 32(4):e13771.
15. Sarosiek I, Selover KH, Katz LA, et al. The assessment of regional gut transit times in healthy controls and patients with gastroparesis using wireless motility technology. Aliment Pharmacol Ther. 2010; 31(2):313-322.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Camilleri M, Parkman HP, Shafi MA, et al. American College of Gastroenterology. Clinical guideline: management of gastroparesis. Am J Gastroenterol. 2013; 108(1):18-37.
2. Lacy BE, Tack J, Gyawali CP. AGA Clinical practice update on management of medically refractory gastroparesis: Expert review. Clin Gastroenterol Hepatol. 2022; 20(3):491-500.
3. Rao SS, Camilleri M, Hasler WL, et al. Evaluation of gastrointestinal transit in clinical practice: position paper of the American and European Neurogastroenterology and Motility Societies. Neurogastroenterol Motil. 2011b.
4. Stein E, Berger Z, Hutfless S, et al. Wireless Motililty Capsule Versus Other Diagnostic Technologies for Evaluating Gastroparesis and Constipation: A Comparative Effectiveness

Review [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2013 May. Available at: https://www.ncbi.nlm.nih.gov/books/NBK154643/.
5. U.S. Food and Drug Administration. 510(k) Summary: K053547. January 10, 2017. Available at:www.accessdata.fda.gov/cdrh_docs/pdf5/k053547.pdf.

Websites for Additional Information

1. American College of Gastroenterology. Gastroparesis. Available at: https://gi.org/topics/gastroparesis/.
2. American Neurogastroenterology and Motility Society. Information on GI motility tests and procedures Available at. https://motilitysociety.org/page.php?id=238.

Policy History

Original Effective Date: 06/17/2015
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06/04/2015	Medical Policy Committee review
06/17/2015	Medical Policy Implementation Committee approval. New policy.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
06/02/2016	Medical Policy Committee review
06/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
06/01/2017	Medical Policy Committee review
06/21/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/06/2019	Medical Policy Committee review
06/19/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/04/2020	Medical Policy Committee review
06/10/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/03/2021	Medical Policy Committee review
06/09/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/02/2022	Medical Policy Committee review
06/08/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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06/01/2023 Medical Policy Committee review
06/14/2023 Medical Policy Implementation Committee approval. Title changed from Ingestible pH and Pressure Capsule to Wireless Capsule for the Evaluation of Suspected Gastric and Intestinal Motility Disorders. Coverage changed to "Based on review of available data, the Company considers a wireless capsule (SmartPill Motility Testing System) for evaluation of all conditions including, but not limited to the following to be investigational:
- Suspected gastric motility disorders (e.g., gastroparesis); or
- Suspected intestinal motility disorders (e.g., constipation)."

08/01/2024 Medical Policy Committee review
08/14/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 08/2025

Coding

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	91112
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.