Complementary and Alternative Medicine (CAM) Treatments

MEDICARE MEDICAL POLICY NUMBER: 327

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INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Important Notes:

- Member benefits, which address coverage or non-coverage of specific complementary and alternative medicine treatments, may vary. Member evidence of coverage (EOC) language takes precedent over medical policy.
- Services in this policy may exist in other Medical Policies. See Cross References for guidance.

Service	Medicare Guidelines
Acupuncture (includes dry needling)	Medically necessary acupuncture services: • National Coverage Determinations (NCD): Acupuncture for Chronic Lower Back Pain (cLBP) (30.3.3) Other acupuncture services*: • NCD: Acupuncture (30.3) • NCD: Acupuncture for Fibromyalgia (30.3.1) • NCD: Acupuncture for Osteoarthritis (30.3.2) ***NOTES**: 1. **Dry Needling:** CMS considers dry needling to be a type of acupuncture. *(National Coverage Analysis for Acupuncture for Chronic Low Back Pain, CAG-00452N)* 2. Individual member benefits determine coverage of acupuncture services. All Medicare Advantage members are provided coverage of acupuncture for ***cLBP*** as set forth by the provisions and limits found in the NCD 30.3.3. However, coverage of acupuncture services for conditions ***other than*** cLBP is only available for members with a supplemental benefit for routine acupuncture services. For members who do not have the supplemental benefit for routine acupuncture services, the above NCDs (30.3, 30.3.1, and 30.3.2) apply. It is recommended

	that Plan members familiarize themselves with the benefit limits of their health plan for acupuncture services to avoid unexpected denials.
Cellular Therapy (M0075)	NCD: Cellular Therapy (30.8)
Colonic Irrigation (Lavage) (0736T)	NCD: Colonic Irrigation (100.7)
Massage Therapy (of any form, including TuiNa) (CPT 97124)	Massage given by an occupational therapist as part of ongoing treatment and therapy or by a chiropractor for preparatory purposes during a chiropractic visit may be considered medically necessary; however, massage therapy itself is not a covered benefit under Medicare or for Medicare Advantage plans. In addition, massage therapy is not a service that is eligible to be offered by Medicare Advantage plans as a supplemental benefit, even if furnished by a state licensed massage therapist. *(Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §30.4 – Items and Services Not Eligible as Supplemental Benefits)*
Naturopaths and Other Providers Ineligible for Medicare Participation	Services may be excluded from coverage due to being rendered by a provider who is ineligible for Medicare participation. Examples of providers ineligible to participate in the Medicare program, and therefore, are ineligible for Medicare reimbursement, include – but are not limited to – the following: • Acupuncturist • Birthing Center • Licensed Massage Therapist • Marriage Family Therapist • Naturopath **NOTE:** This does **not** mean non-covered CAM treatments are covered when performed by a Medicare-eligible provider. Non-covered services are non-covered regardless of the provider type.
Over-the-Counter products	Medicare Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements, §10.10 – Over-the-Counter Products (OTCs)
Topical Oxygen Therapy (E0466, A4575, 99199)	• **DME (E0446/A4575):** Local Coverage Determination (LCD): Oxygen and Oxygen Equipment (L33797) • **Physician services (CPT 99199):** Local Coverage Article (LCA): Billing and Coding: Topical HBO and Physician Related Service Billing and Coding Guidelines (A56026) *(According to this LCA, "there shall be no coverage for any separate or additional payment for any physician's professional services related to this procedure.")*

	NOTE: For all other oxygen therapies, including ozone therapy administered directly to the tissue, intravenously, or intramuscularly, see Company policy criteria below.
Prescription vitamins, minerals, and dietary supplements	Medicare Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements, §20.1 – Excluded Categories
Products which do not have U.S. Food and Drug (FDA) Approval	According to the *Medicare Benefit Policy Manual, Chapter 14,* while U.S. Food and Drug Administration (FDA) approval does not automatically guarantee *coverage* under Medicare, in order to even be considered for coverage under Medicare, devices must be FDA-approved, when such products are subject to this oversight and approval. Any device or product which has not received FDA-approval would not be considered medically reasonable or necessary. While the FDA reviews data from well-designed studies and clinical trials in order to determine safety and effectiveness prior to approval for sale, the FDA does not establish medical necessity of that device or drug for Medicare beneficiaries. Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under *§1862(a)(1)(A)*.
Thermogenic Therapy	NCD: Thermogenic Therapy (30.2)
Transcendental Meditation (TM)	NCD: Transcendental Meditation (30.5)

Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria… when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." *(§ 422.101(b)(6) – see Policy Guidelines below*)

- **Medicare Coverage Manuals:** Medicare does not have criteria specific to any of the CAM treatments noted below in a coverage manual.
- **National Coverage Determination (NCD):** Medicare does not have an NCD for any of the CAM treatments noted below.
- **Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** As of the most recent policy review, no Medicare Administrative Contractors (MACs) have LCDs for most of the CAM treatments noted below (two MACs call out craniosacral therapy as non-covered, and one MAC has a non-coverage LCD for topical oxygen therapy, but none of these MACs are the MAC for the plan service area).
- Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(6)(i)(C) as there is no Medicare coverage criteria available. **However, Medicare's non-coverage position for most alternative medicine services is well established.** Any coverage that may be provided is "above and beyond" coverage provided by Original Medicare.
- ***NOTE:*** *The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].*

All other CAM services not otherwise addressed, including: *Non-antimicrobial alternative therapies for Lyme disease* *Therapeutic phlebotomy* *Autogenous lymphocytic factor* *Intravenous infusion procedures using products such as hydrogen peroxide, micronutrients (Myers' cocktail), vitamin C, etc.* *Active release techniques®* *Craniosacral therapy (CST)* *Cupping* *Instrument assisted soft tissue mobilization (IASTM), including but not limited to the Graston Technique®* *Mesotherapy* *Other oxygen therapy not otherwise addressed, including ozone therapy administered directly to the tissue, intravenously, or intramuscularly* *Placentophagy/placenta capsules*	Company medical policy for Complementary and Alternative Medicine (CAM) Treatments I. These services may be considered **medically necessary** for Medicare when the Company medical policy criteria are met. II. These services are considered **not medically necessary** for Medicare Plan members either when the Company medical policy criteria are **not** met ***or*** when a service is deemed "not medically necessary" by the Company policy. See *Policy Guidelines below.*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those

considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

- Biofeedback and Neurofeedback, MP515
- Hyperbaric Oxygen Therapy, MP198

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

Complementary and alternative medicine (CAM) are approaches to care that are not in the mainstream stand of care approach. **Complementary** treatments are used *along with* standard medical treatments but are not themselves considered to be standard treatment. **Alternative** treatments are used *instead of* standard treatments and may intend to replace mainstream approaches. These treatments may be practiced by those who hold medical degrees, but they may also be practiced by those who specialize in allopathic, or Western medicine. Not only must the service in question meet Medicare's "reasonable and necessary" requirements, but the provider of the service must also be an eligible provider of Medicare services.

MEDICARE AND MEDICAL NECESSITY

For Medicare, only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. *(§ 422.101(c)(1))*

In addition:

> "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or

> meta-analyses summarizing the literature of the specific clinical question.” *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare’s definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan’s use of evidence-based processes for policy development.

Most CAM treatments are not called addressed within a Medicare coverage policy directly; however, as of the date of the most recent review, two MACs (CGS and National Government Services) do call out craniosacral therapy as a non-covered procedure within their outpatient PT/OT LCDs, and Palmetto GBA has a non-coverage LCD for topical oxygen therapy. Since there are not fully established coverage criteria for either non-antimicrobial therapies for Lyme disease or for therapeutic phlebotomy available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied. See the Medicare Coverage Criteria table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

Therapeutic Phlebotomy (CPT Code 99195)

Therapeutic phlebotomy (CPT 99195) may only be considered medically necessary when billed with the indications/diagnosis codes listed below. Claims billed with a diagnosis code not listed here will be denied as “not medically necessary.”

Polycythemia Vera

D45	Polycythemia vera
D75.0	Familial erythrocytosis

Hemochromatosis

E83.11	Hemochromatosis
E83.110	Hereditary hemochromatosis

83.111	Hemochromatosis due to repeated red blood cell transfusions
83.118	Other hemochromatosis
E83.119	Hemochromatosis, unspecified

Iron Overload

E83.1	Disorders of iron metabolism
E83.10	Disorders of iron metabolism, unspecified
E83.19	Other disorders of iron metabolism
T45.4X1	Poisoning by iron and its compounds, accidental
T45.4X1A	Poisoning by iron and its compounds, accidental, initial encounter
T45.4X1D	Poisoning by iron and its compounds, accidental, subsequent encounter
T45.4X1S	Poisoning by iron and its compounds, accidental, sequela
T45.4X2	Poisoning by iron and its compounds, intentional self-harm
T45.4X2A	Poisoning by iron and its compounds, intentional self-harm, initial encounter
T45.4X2D	Poisoning by iron and its compounds, intentional self-harm, subsequent encounter
T45.4X2S	Poisoning by iron and its compounds, intentional self-harm, sequela
T45.4X3	Poisoning by iron and its compounds, assault
T45.4X3A	Poisoning by iron and its compounds, assault, initial encounter
T45.4X3D	Poisoning by iron and its compounds, assault, subsequent encounter
T45.4X3S	Poisoning by iron and its compounds, assault, sequela
T45.4X4	Poisoning by iron and its compounds, undetermined
T45.4X4A	Poisoning by iron and its compounds, undetermined, initial encounter
T45.4X4D	Poisoning by iron and its compounds, undetermined, subsequent encounter
T45.4X4S	Poisoning by iron and its compounds, undetermined, sequela
T45.4X5	Adverse effect of iron and its compounds
T45.4X5A	Adverse effect of iron and its compounds, initial encounter
T45.4X5D	Adverse effect of iron and its compounds, subsequent encounter
T45.4X5S	Adverse effect of iron and its compounds, sequela
R79.0	Abnormal level of blood mineral
D75.8	Other specified disease of blood and blood-forming organs
D75.89	Other specified disease of blood and blood-forming organs

Erythrocytosis

D75.1	Secondary polycythemia
D75.8	Other specified disease of blood and blood-forming organs
D75.89	Other specified disease of blood and blood-forming organs
C22.0	Liver cell carcinoma
D09.1	Carcinoma in situ of other and unspecified urinary organs
D09.10	Carcinoma in situ of unspecified urinary organ
D09.19	Carcinoma in situ of other urinary organs
C64	Malignant neoplasm of kidney, except renal pelvis
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis

C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis

Porphyria

E80.0	Hereditary erythropoietic porphyria
E80.1	Porphyria cutanea tarda
E80.2	Other and unspecified porphyria
E80.20	Unspecified porphyria
E80.29	Other porphyria

HCPCS Code M0075

The *National Physician Fee Schedule Relative Value File (NPFSRVF)*, which is published by Medicare[1], indicates HCPCS code M0075 has been assigned a Status Indicator of "N," which is defined as "Non-covered Services." This is a statutorily excluded service based on NCD 30.8.

HCPCS Codes S9494-S9504

Like all S-codes, the NPFSRVF also indicates HCPCS codes S9494-S9504 have been assigned a Status Indicator of "I." This is defined as "Not valid for Medicare purposes." In addition, HCPCS codes S9494-S9504 are not recognized as a valid code for claim submission as indicated in the relevant Company Coding Policy *(HCPCS S-Codes and H-Codes,* 22.0*).* Providers need to use alternate available CPT or HCPCS codes to report for the service. If no specific CPT or HCPCS code is available, then an unlisted code may be used. Note that unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. Thus, if an unlisted code is billed related to a non-covered service addressed in this policy, it will be denied as not covered.

CODES*		
CPT	0736T	Colonic lavage, 35 or more liters of water, gravity-fed, with induced defecation, including insertion of rectal catheter
	20560	Needle insertion(s) without injection(s); 1 or 2 muscle(s)
	20561	Needle insertion(s) without injection(s); 3 or more muscles
	45399	Unlisted procedure, colon
	96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour
	96361	Intravenous infusion, hydration; each additional hour (List separately in addition to code for primary procedure)
	96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
	96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
	96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)

	96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (List separately in addition to code for primary procedure)
	96369	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); initial, up to 1 hour, including pump set-up and establishment of subcutaneous infusion site(s)
	96370	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
	96371	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); additional pump set-up with establishment of new subcutaneous infusion site(s) (List separately in addition to code for primary procedure)
	96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
	96373	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intra-arterial
	96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug
	96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)
	96376	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/drug provided in a facility (List separately in addition to code for primary procedure)
	96377	Application of on-body injector (includes cannula insertion) for timed subcutaneous injection
	96379	Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion
	97039	Unlisted modality (specify type and time if constant attendance)
	97124	Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)
	97140	Manual therapy techniques (eg, mobilization/ manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes
	97810	Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
	97811	Acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)
	97813	Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal oneon-one contact with the patient
	97814	Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)
	98925	Osteopathic manipulative treatment (OMT); 1-2 body regions involved
	98926	Osteopathic manipulative treatment (OMT); 3-4 body regions involved
	98927	Osteopathic manipulative treatment (OMT); 5-6 body regions involved
	98928	Osteopathic manipulative treatment (OMT); 7-8 body regions involved
	98929	Osteopathic manipulative treatment (OMT); 9-10 body regions involved
	99195	Phlebotomy, therapeutic (separate procedure)

	99601	Home infusion/specialty drug administration, per visit (up to 2 hours)
	99602	Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour (List separately in addition to code for primary procedure)
HCPCS	M0075	Cellular therapy *(CMS-assigned Status Code "N")*
	S9494 - S9504	Home infusion therapy *(CMS-assigned Status "I" codes – See above billing guidelines)*

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Medicare Physician Fee Schedule (PFS) Relative Value Files; Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files
2. National Institutes of Health. National Cancer Institute. Complementary and Alternative Medicine. Updated: June 12, 2023. https://www.cancer.gov/about-cancer/treatment/cam. Accessed 09/11/2024.
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4. National Institutes of Health. National Center for Complementary and Integrative Health (NCCIH). The Use and Cost of Complementary Health Approaches in the United States. https://www.nccih.nih.gov/about/the-use-and-cost-of-complementary-health-approaches-in-the-united-states. Accessed 09/11/2024.
5. National Institutes of Health. National Center for Complementary and Integrative Health (NCCIH). NCCIH Strategic Plan FY 2021-2025. https://www.nccih.nih.gov/about/nccih-strategic-plan-2021-2025. Accessed 09/11/2024.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY

11/2022	Annual review (converted to new format 2/2023)
4/2023	Interim update, added therapeutic phlebotomy to the policy
1/2024	Annual review; no criteria changes but language revision due to policy changes from “Investigational” to “not medically necessary”, update title, add code for colonic lavage
11/2024	Annual review; no criteria changes