Medicare Medical Policy

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, Providence Plan Partners, and Ayin Health Solutions 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	Potentially covered acupuncture services: • National Coverage Determinations (NCD): Acupuncture for Chronic Lower Back Pain (cLBP) (30.3.3) Non-covered acupuncture services: • NCD: Acupuncture (30.3) • NCD: Acupuncture for Fibromyalgia (30.3.1) • NCD: Acupuncture for Osteoarthritis (30.3.2)
Cellular Therapy (M0075)	NCD: Cellular Therapy (30.8)
Colonic Irrigation	NCD: Colonic Irrigation (100.7)
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 CAM treatments are covered when performed by a Medicare-eligible provider.
Over-the-Counter products	Medicare Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements, §10.10 - Over-the-Counter Products (OTCs)
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)
Non-antimicrobial alternative therapies for Lyme disease	Company medical policy for Complementary and Alternative Medicine (CAM) Treatments I. These services are considered **not medically necessary** for Medicare Plan members, based on the Company medical policy. *Services deemed "investigational" are considered not medically necessary for Medicare Plan members. 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 (Medicare Only), MP270
- Chelation Therapy for Non Overload Conditions (Medicare Only), MP102
- Chiropractic Care (Medicare Only) MP243

- Hyperbaric Oxygen Therapy (Medicare Only), MP198
- Subcutaneous Hormone Pellet Implant, MP109

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.

MEDICARE AND MEDICAL NECESSITY

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. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.), Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. *(Medicare Managed Care Manual, Ch. 4, §90.5)*

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be "investigational." The term "investigational" is not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), but rather may also mean the procedure, device, or technology does not meet all of the Company's technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5).

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)*. Thus, services which lack scientific evidence regarding safety and efficacy because they are investigational are "not medically reasonable or necessary" for Medicare Plan members. *(Medicare Claims Processing Manual, Ch. 23, §30 A)*

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

Like all S-codes, the *National Physician Fee Schedule Relative Value File (NPFSRVF)*, which is published by the Centers for Medicare and Medicaid Services (CMS)[1], 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	45399	Unlisted procedure, colon
	96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour
	96361	; 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	; each additional hour (List separately in addition to code for primary procedure)
	96367	; additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)
	96368	; 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	; each additional hour (List separately in addition to code for primary procedure)
	96371	; 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	; each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)
	96376	; 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
	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
	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 *(Medicare-assigned Status Code "N")*
	S9494 - S9504	Home infusion therapy

***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: March 21, 2022. https://www.cancer.gov/about-cancer/treatment/cam. Accessed 09/09/2022.
3. National Institutes of Health. National Center for Complementary and Integrative Health (NCCIH). Complementary, Alternative, or Integrative Health: What's In a Name? Last Updated: April 2021. https://www.nccih.nih.gov/health/complementary-alternative-or-integrative-health-whats-in-a-name. Accessed 09/09/2022.

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 09/09/2022.
5. National Institutes of Health. National Center for Complementary and Integrative Health (NCCIH). NCCIH 2016 Strategic Plan. https://www.nccih.nih.gov/about/nccih-2016-strategic-plan. Accessed 09/09/2022.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
11/2022	Annual review (converted to new format 2/2023)