Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Experimental & Investigational Services		
MNG #: 010	**☒SCO ☒One Care** **☒ MAPD-MA Medicare Preferred** **☒ MAPD-MA Medicare Value** **☒ MAPD-RI Medicare Preferred** **☒ MAPD-RI Medicare Value** **☒ DSNP-RI Medicare Maximum**	**Prior Authorization Needed?** **☒Yes ☐No**
Clinical: ☒	**Operational: ☐**	**Informational: ☐**
Medicare Benefit: **☐Yes ☒No**	**Approval Date:** 1/28/2019;	**Effective Date:** 4/01/2019;
Last Revised Date: 1/29/2019; 08/05/2020, 10/16/2020; 11/05/2020; 04/01/2021; 05/13/2021; 05/18/2021; 08/04/2021; 08/19/2021; 9/2/2021	**Next Annual Review Date:** 08/05/2021; 11/05/2021; 04/01/2022; 05/13/2022; 05/18/2022; 08/04/2022; 08/19/2022; 9/2/2022	**Retire Date:**

OVERVIEW:

Experimental, investigational or unproven service (EIS) may refer to a service (e.g. treatment), procedure (e.g. test or intervention), or supply (e.g. drug, device or equipment) that is not accepted by the professional medical community as the standard practice or therapy. Commonly, there is insufficient *authoritative or reliable evidence* for the EIS and its absolute risk (in terms of safety and effectiveness) to permit conclusions to be drawn for the effect of the treatment on health outcomes. As such, the EIS is part of ongoing studies to determine its safety, effectiveness, toxicity, maximum tolerated dose, and efficacy compared to a generally accepted means of diagnosis or treatment.

To make coverage determinations on EIS, Commonwealth Care Alliance (CCA) will utilize pertinent medical necessity guidelines; and review related information from government regulatory bodies, accrediting organizations, and scientific evidence. This may include guidance from the Center for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA), MassHealth, InterQual, National Committee for Quality Assurance (NCQA), authoritative or reliable evidence, and actively practicing specialty physicians. This will ensure that the coverage of EIS is consistent and clinically appropriate (in terms of type, frequency, extent, site, and duration) for the prevention, diagnosis, and treatment of the condition (which includes disease, illness, or disability).

DEFINITIONS:

Authoritative or Reliable Evidence: Authoritative or reliable evidence refer to:

- Reports and articles that are derived from well-designed, well-conducted and scientifically valid studies that are published in credible, medical and scientific research journals,
- Peer-reviewed publications that have been assessed by medical or scientific experts prior to publication,
- Evaluations of evidence that have considered the consistency of results and quality of published studies,
- Guidelines and recommendations made by national medical associations, reputable technology assessment bodies, and healthcare professionals with recognized clinical expertise in treating the medical condition and/or providing the treatment
- Examples of acceptable sources of peer-reviewed medical literature include (this is not an exhaustive list):

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- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Blood
- British Medical Journal
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of Urology
- Lancet
- The New England Journal of Medicine
- Annals of General Surgery

Experimental, Investigational or Unproven Services (EIS): Experimental, investigational or unproven services may refer to but not limited to a drug, test, procedure, treatment, device, or equipment that remains under study as its absolute risk is unestablished. Further study is required to determine the safety, effectiveness, toxicity, maximum tolerated dose, and efficacy of the EIS. It is generally not the standard therapy, therefore, not accepted by the professional medical community.

Generally Accepted Standards of Medical Practice: Standards that are based on credible scientific data, are published in peer-reviewed medical/scientific literature, are recognized by the relevant medical community, and align with physician specialty society recommendations and views of physicians practicing in the relevant clinical areas.

Medically Necessary: A service is "medically necessary" if:

(1) it is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member that endanger life, cause suffering or pain, cause physical deformity or malfunction, threaten to cause or to aggravate a handicap, or result in illness or infirmity; **and**

(2) There is no other medical service or site of service, comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly. Services that are less costly or more conservative include, but are not limited to, health care reasonably known by the provider, or identified by CCA pursuant to a prior authorization request, to be available to the member through the requesting provider or from another provider who is available to treat the member.

Not Medically Necessary: A healthcare service or product is considered not medically necessary when it is provided primarily for the convenience of the patient, physician, or other healthcare provider, and is more costly than an alternative service or sequence of services that may produce equivalent therapeutic or diagnostic effect in the diagnosis or treatment of the member's specific illness or disease. These healthcare service or product may be in accordance with generally accepted standards of medical practice and/or be clinically appropriate.

DECISION GUIDELINES:

Commonwealth Care Alliance will not cover services, procedures, and/or supplies that are considered experimental, investigational or unproven AND *not medically necessary* according to the following criteria:

- The service, procedure, or supply does not have final and/or unrestricted market approval from the FDA or from any other governmental regulatory body,

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- Further study is required to determine the safety, efficacy, toxicity, or maximum tolerated dose for the service, procedure, or supply,
- There is insufficient authoritative evidence to allow for the evaluation of the therapeutic value of the service, procedure, or supply,
- There is insufficient authoritative evidence to permit the evaluation of *net health outcomes*,
- There is insufficient authoritative evidence that the service, procedure, or supply has a beneficial effect on health outcomes or is as beneficial as other alternative interventions or therapies, when used in a non-investigational setting,
- The service, procedure, or supply is not as beneficial as established alternative interventions or therapies, AND
- The service, procedure, or supply is not in accordance with *generally accepted standards of medical practice* or not generally accepted by in the professional medical community as safe and effective in the setting and condition for which it is used

Commonwealth Care Alliance may cover services, procedures, and/or supplies that are considered experimental, investigational or unproven when they meet the following criteria:

- The service, procedure, or supply request is evaluated by a CCA medical director,
- The service, procedure, or supply is determined to be *medically necessary* in accordance with the definition, regulatory and professional standards, and authoritative evidence,
- The medical necessity for the service, procedure, or supply is substantiated by:
    - Documentation to support that the service, procedure, or supply is medically necessary, AND
    - Complete copies (in full-text) of supporting peer-reviewed literature to indicate that the service, procedure, or supply is,
        - Safe and efficacious,
        - Generally accepted by the professional medical community,
        - Regarded or accepted as a comparable treatment for the member's underlying disease, AND
        - The most conservative or least costly alternative

    OR

    - Documentation that indicates that the service, procedure, or supply is:
        - The best treatment choice for the member due to their specific unique clinical circumstances,
        - Standard therapies have been tried and not been effective OR have been determined to not be medically appropriate,
        - There is reason to believe that the intervention requested will be successful when other treatments have failed
    - Complete copies (in full-text) of supporting peer-reviewed literature to indicate that the service, procedure, or supply is safe and efficacious

The hierarchy of authoritative evidence that will be used to determine whether the service, procedure, or supply is safe and efficacious, generally accepted by the professional medical community, and regarded or accepted as a comparable treatment for the member's underlying disease, is:

- Published formal technology assessments and/or high quality meta-analyses,
- Well-designed randomized studies published in credible, peer-reviewed literature,
- High quality case-control or cohort studies,
- Historical control studies, case reports, and/or case series,

- Reports of expert opinion from national professional medical societies or national medical policy organizations

LIMITATIONS/EXCLUSIONS:

Commonwealth Care Alliance limits coverage to EIS services, procedures, or supplies wherein medical necessity has been determined, safety and efficacy has been established, and therapeutic benefit is comparable with standard treatment, evidenced by authoritative evidence. Reports, articles or statements from providers that contain only abstracts, anecdotal evidence, or personal professional opinions is not considered authoritative evidence.

Commonwealth Care Alliance will not cover the following EIS services, procedures, or supplies in the following list of procedure and/or diagnosis codes below. Information related to the list include:

- The following CPT/HCPCS procedure codes are considered as EIS and are generally not covered,
- The list is intended to be used as a reference and for informational purposes,
- When it states, there is "no specific code available" this indicates that it is an "unlisted code" or "miscellaneous code,"
- When it states, "EIU (experimental, investigational, or unproven)" in the third column of the list, non-coverage is implied, AND
    - Note: Codes of related therapy for similar conditions may be non-covered as an EIU
- The list is not all inclusive and may change as emerging evidence becomes available

AUTHORIZATION:

Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the servicearea who are medical experts in the appropriate field, review of FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions. If at any time a CMS Local or National Coverage Determination (LCD or NCD) is published that conflicts with the criteria set forth herein, the NCD or LCD criteria shall supersede these criteria.

Code	Description	Details
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling	EIU for K59.00, R10.2, R33.9, N39.3, G62, G64, G90, 356.9, E10.43, K31.84, Z4542, M54.81, R51, G43, G44
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver	EIU for K59.00, R10.2, R33.9, N39.3, G62, G64, G90, 356.9, E10.43, K31.84, Z4542, M54.81, R51, G43, G44
90868	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session	EIU EXCEPT for F32.2, F33.2

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Code	Description	Details
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays	EIU EXCEPT for G20, G21.4, G24.1, G25.0-G25.2,G40.011-G40.019;G40.111-G40.119;G40.211-G40.219,G40.311-G40.319,G40.813, G40.814,G40.A11, G40.A19
G0283	*Electrical Stimulation (Unattended), To One Or More Areas For Indication(S) Other Than Wound Care, As Part Of A Therapy Plan Of Care*	EIU for N39, R32, R15
64568	Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator	EIU EXCEPT for G40.011-G40.019; G40.211-G40.219, G40.311-G40.319, G40.813, G40.814, G40.A11, G40.A19
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array	EIU EXCEPT for G20, G21.4, G24.1, G25.0- G25.2, G40.011-G40.019; G40.111-G40.119; G40.211-G40.219, G40.311-G40.319, G40.813, G40.814, G40.A11, G40.A19
97014	*Application of a modality to 1 or more areas; electrical stimulation (unattended)*	EIU for N39, R32, R15; ALLOWED for N32.81, N39.15, N39.41, R35.0
64585	Revision or removal of peripheral neurostimulator electrode array	EIU for Z4542, M54.81, R51, G43, G44
56620	Vulvectomy simple; partial	EIU for N90.6
L6880	Electric Hand, Switch Or Myolelectric Controlled, Independently Articulating Digits, Any Grasp Pattern Or Combination Of Grasp Patterns, Includes Motor(S)	EIU
L8701	Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated.	EIU
L8702	Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor,	EIU

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Code	Description	Details
	sensors, all components and accessories, custom fabricated.	
64910	Nerve repair; with synthetic conduit or vein allograft (e.g., nerve tube), each nerve	EIU
C1818	Integrated Keratoprosthesis	EIU
K1006	Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system	EIU
K1007	Powered exoskeletons for ambulation in patients with lower limb disabilities.	EIU
J2001 J3490 **96365** **96366** **96374**	IV Infusions of anesthetics (e.g. ketamine or lidocaine) for the management of: (1) Chronic pain (including but not limited to chronic neuropathic pain, chronic daily headache, and fibromyalgia) (2) Behavioral health conditions (including but not limited to depression, bipolar disorder, post-traumatic stress disorder, autism spectrum disorder, and obsessive-compulsive disorder)	EIU
37243	Prostate Artery Embolization	EIU
33289	Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed.	EIU
93264	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional.	EIU
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components.	EIU

REGULATORY NOTES:

Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the servicearea who are medical experts in the appropriate field, review of FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions. If at any time a CMS Local or National Coverage Determination (LCD or NCD) is published that conflicts with the criteria set forth herein, the NCD or LCD criteria

shall supersede these criteria.

Disclaimer:

This Medical Necessity Guideline is not a rigid rule. As with all of CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity (supporting literature (full text preferred) should be attached to the request), or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

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RELATED REFERENCES:

1. Centers for Medicare & Medicaid Services. (2014). *Guidance for the public, industry, and CMS staff: Coverage with evidence development.* Retrieved from https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27
2. Centers for Medicare & Medicaid Services. (2014). *Medicare benefit policy manual: Chapter 14 medical devices.* Retrieved from https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c14.pdf
3. Centers for Medicare & Medicaid Services. (2015). *Local coverage article: Clinical trials – Medical policy article (A52840*). Retrieved from https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52840&ver=2&DocID=A52840&bc=gAAAABAAAAAA&
4. Centers for Medicare & Medicaid Services. (n.d.). *Medicare & clinical research studies.* Retrieved from https://www.medicare.gov/Pubs/pdf/02226-medicare-and-clinical-research-studies.pdf

ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B	

REVISION LOG:

REVISION DATE	DESCRIPTION
8/4/2021	Overview: Added greater detail to the definition of EIS. Definitions added: Authoritative or reliable evidence, clinical trial, experimental/investigation/unproven services, generally accepted standards of medical practice, medical necessary, net health outcome, not medically necessary, routine costs (in the context of clinical trials). Decision guidelines added: criteria when EIS is not covered and covered, coverage of routine costs for EIS in clinical trials.
5/18/2021	Added in the overview: the review of information from appropriate government regulatory bodies: CMS, Commonwealth of Massachusetts, and FDA.
5/13/2021	Removed CPT codes 0194T and 64566 as there are LCD coverage. Added CardioMEMs as an Experimental and Investigational Service. CPT codes 33289 and 93264, and HCPCS code C2624 added. Added HCPCS code (K1006) for the PureWick Systems.
8/26/2020	Updated approval signature

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APPROVALS:

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CCA Senior Clinical Lead [Print]	**Title [Print]**
	
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