Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Experimental & Investigational Services		
MNG #: 010	**☒SCO ☒One Care**	**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; 05/17/2021; 05/18/2021;6/3/2021	**Next Annual Review Date:** 08/05/2021; 11/05/2021; 04/01/2022; 05/18/2022;6/3/2022	**Retire Date:**

OVERVIEW:

Commonwealth Care Alliance, Inc. (CCA) will determine if a treatment or procedure is considered experimental, investigational or unproven where it is "not generally accepted by the medical community". Experimental, investigational or unproven treatments are interventions or therapies that are under study to determine their safety, efficacy, toxicity, maximum tolerated dose, and its comparative efficacy to a generally accepted means of treatment or diagnosis.

Commonwealth Care Alliance restricts coverage to those devices, treatments, or procedures for which the safety and efficacy have been proven, or where the clinical and scientific evidence indicates that the treatment is at least as beneficial as any established evidence-based alternatives. Any device, medical treatment, supply or procedure for which safety and efficacy has not been established and proven is considered experimental, investigational or unproven; investigational or unproven therapies are not medically necessary and are therefore excluded from coverage, unless they are explicitly covered by Medicare, MassHealth, or by CCA's plan documents. Additionally, CCA will review related information from appropriate government regulatory bodies including the Food and Drug Administration (FDA) and the Center for Medicare and Medicaid Services (CMS)

DECISION GUIDELINES:

To determine whether a device, medical treatment, supply or procedure is proven safe and effective the following hierarchy of reliable evidence is used:

1. Published formal technology assessments and/or high quality meta analyses.
2. Well-designed randomized studies published in credible, peer-reviewed literature.
3. High quality case-control or cohort studies.
4. Historical control studies, or case reports and/or case series.
5. Reports of expert opinion from national professional medical societies or national medical policy organizations.

With respect to clinical studies, only those reports and articles containing scientifically valid data and published in the refereed (also known as 'peer reviewed') medical and scientific literature shall be considered reliable evidence. Specifically, not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence or personal professional opinions. Also, not included is the fact that a provider or a number of providers have elected to adopt a device, medical treatment, or procedure as their personal treatment or procedure of choice or standard of practice.

Medical Necessity Guideline

DEFINITION:

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.

AUTHORIZATION:

Requests for experimental treatments or procedures will be evaluated by CCA by a medical director to determine ifthe requested services are medically necessary in accordance with the above definition, applicable regulatory and professional standards, and the below criteria.

CCA has determined through its medical policy review process that the experimental services listed on this medical necessity guideline are not generally accepted by the medical community. Medical necessity for these services must therefore be substantiated by medical records including evidence of medical necessity, accompanied by complete copies of supporting peer-reviewed literature* indicating that the requested service is widely and generally accepted by the medical community (including appropriate specialty communities) as a comparable treatment for the member's underlying disease and is the most conservative or least costly alternative,

OR

Records indicating that it is the best treatment choice for the member because of their specific, unique clinical circumstances, or because all other treatment options have been exhausted, **and** there is reason to believe that the intervention requested will be successful even though other treatments have failed; peer-reviewed literature revealing some evidence of efficacy (even if not otherwise sufficient to allow coverage) will be required.

*Examples of acceptable sources of medical literature include (this is not an exhaustive list):

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

Medical Necessity Guideline

Journal of the National Cancer Institute
Journal of Urology
Lancet
The New England Journal of Medicine
Annals of General Surgery

Requesting providers should send complete copies of supporting literature articles for consideration by the Plan in requests for authorization pursuant to this medical necessity guideline; abstracts alone will generally not be sufficient to permit review.

LIMITATIONS/EXCLUSIONS:
The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not signify whether the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply. This Medical Necessity Guideline is subject to all applicable laws and regulations, Plan Policies and Guidelines, including requirements for prior authorization and other requirements in Provider's agreement with the Plan (including complying with Plan's Provider Manual specifications).

The following CPT/HCPCS procedure codes are experimental, investigational, or unproven, and are therefore generally not covered.

Note: 'No specific code available' indicates an "unlisted code" or "miscellaneous code." This list is not intended to be exhaustive.

Where EIU (experimental, investigational, or unproven) is indicated in the third column (Details), non-coverage is implied. Codes of related or similar therapy for similar conditions may also generally be non-covered as and EIU device or service.

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,

Medical Necessity Guideline

		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
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

Medical Necessity Guideline

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, sensors, all components and accessories, custom fabricated.	EIU
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

	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

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.

ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B	

REVISION LOG:

REVISION DATE	DESCRIPTION
5/18/2021	Added in the overview: the review of information from appropriate government regulatory bodies: CMS, Commonwealth of Massachusetts, and FDA.
5/17/2021	Added HCPCS code (K1006) for the PureWick Systems.
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.
8/26/2020	Updated approval signature

Medical Necessity Guideline

APPROVALS:

Douglas Hsu, MD, MPH	Vice President, Medical Policy and Utilization Review
CCA Senior Clinical Lead [Print]	**Title [Print]**
Signature	**Date**
Click here to enter text.	
CCA Senior Operational Lead [Print]	**Title [Print]**
Signature	**Date**
Lori Tishler, MD	Senior Vice President, Medical Services
CCA CMO or Designee [Print]	**Title [Print]**
Lori Tishler	
Signature	**Date**