



## Medical Necessity Guideline

<b>Medical Necessity Guideline (MNG) Title: Experimental &amp; Investigational Services</b>		
<b>MNG #: 010</b>	<input checked="" type="checkbox"/> SCO <input checked="" type="checkbox"/> One Care	<b>Prior Authorization Needed?</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<b>Clinical:</b> <input checked="" type="checkbox"/>	<b>Operational:</b> <input type="checkbox"/>	<b>Informational:</b> <input type="checkbox"/>
<b>Medicare Benefit:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>Approval Date:</b> 1/28/2019;	<b>Effective Date:</b> 4/01/2019;
<b>Last Revised Date:</b> 1/29/2019; 08/05/2020, 10/16/2020; 11/05/2020; 04/01/2021; 05/13/2021	<b>Next Annual Review Date:</b> 08/05/2021; 11/05/2021; 04/01/2022; 05/13/2022	<b>Retire Date:</b>

**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 treatments which are under study to determine their safety, efficacy, toxicity, maximum tolerated dose, or if it is under study to determine its efficacy compared 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.

**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 if the 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



### Medical Necessity Guideline

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
<b>90868</b>	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session	EIU EXCEPT for F32.2, F33.2
<b>61886</b>	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
<b>G0283</b>	<i>Electrical Stimulation (Unattended), To One Or More Areas For Indication(S) Other Than Wound Care, As Part Of A Therapy Plan Of Care</i>	EIU for N39, R32, R15
<b>64568</b>	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
<b>61885</b>	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

<b>97014</b>	<i>Application of a modality to 1 or more areas; electrical stimulation (unattended)</i>	EIU for N39, R32, R15; ALLOWED for N32.81, N39.15, N39.41, R35.0
<b>64585</b>	Revision or removal of peripheral neurostimulator electrode array	EIU for Z4542, M54.81, R51, G43, G44
<b>56620</b>	Vulvectomy simple; partial	EIU for N90.6
<b>L6880</b>	Electric Hand, Switch Or Myoelectric Controlled, Independently Articulating Digits, Any Grasp Pattern Or Combination Of Grasp Patterns, Includes Motor(S)	EIU
<b>L8701</b>	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
<b>L8702</b>	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
<b>64910</b>	Nerve repair; with synthetic conduit or vein allograft (e.g., nerve tube), each nerve	EIU
<b>C1818</b>	Integrated Keratoprosthesis	EIU
<b>K1007</b>	Powered exoskeletons for ambulation in patients with lower limb disabilities.	EIU
<b>J2001</b> <b>J3490</b> <b>96365</b> <b>96366</b> <b>96374</b>	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



### Medical Necessity Guideline

	Prostate Artery Embolization	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
8/26/2020	Updated approval signature

**APPROVALS:**

Stefan Topolski, MD  
CCA Senior Clinical Lead [Print]

Medical Director, CG West  
Title [Print]

*Stefan Topolski*

8/5/2020

Signature

Date



**Medical Necessity Guideline**

\_\_\_\_\_  
CCA Senior Operational Lead [Print]

\_\_\_\_\_  
Title [Print]

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Lori Tishler, MD

\_\_\_\_\_  
SVP, Medical Services



