

# Medical Necessity Guidelines: Experimental, Investigational or Unproven Services (Commercial & Medicare)



POLICY NUMBER	LAST REVIEW DATE	APPROVED BY
MG.MM.AD.11a	1/11/2022	MPC (Medical Policy Committee)

## **IMPORTANT NOTE ABOUT THIS MEDICAL POLICY:**

*Property of ConnectiCare, Inc. All rights reserved. The treating physician or primary care provider must submit to ConnectiCare, Inc. the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, ConnectiCare will not be able to properly review the request for prior authorization. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. The clinical review criteria expressed below reflects how ConnectiCare determines whether certain services or supplies are medically necessary. ConnectiCare established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). ConnectiCare, Inc. expressly reserves the right to revise these conclusions as clinical information changes; and welcomes further relevant information. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. Each benefit plan defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by ConnectiCare, as some plans exclude coverage for services or supplies that ConnectiCare considers medically necessary. If there is a discrepancy between this guideline and a member's benefits plan, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of the State of CT and/or the Federal Government. Coverage may also differ for our Medicare members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Coverage Determinations (LCD) and/or Local Medical Review Policies (LMRP). All coding and web site links are accurate at time of publication.*

## **Overview:**

ConnectiCare, Inc. defines the terms "investigational" or "experimental" as the use of a service, procedure or supply that is not recognized by the Plan as standard medical care for the condition, disease, illness or injury being treated. A service, procedure or supply includes, but is not limited to the diagnostic service, treatment, facility, equipment, drug or device.

## **Medical Necessity Guidelines:**

A service is considered investigational (experimental) if any of the following criteria are met:

1. The services, procedures or supplies requiring Federal or other Governmental body approval, such as drugs and devices, do not have unrestricted market approval from the Food and Drug Administration (FDA) or final approval from any other governmental regulatory body for use in treatment of a specified condition. Any approval that is granted as an interim step in the regulatory process is not a substitute for final or unrestricted market approval.
2. There is insufficient or inconclusive medical and scientific evidence to permit the Plan to evaluate the therapeutic value of the service, procedure or supply. (Adequate evidence is defined as at least two documents of medical and scientific evidence that indicate that the proposed treatment is likely to be beneficial to the member.)

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3. There is inconclusive medical and scientific evidence in peer-reviewed medical literature that the service, procedure or supply has a beneficial effect on health outcomes.
4. The service, procedure or supply under consideration is not as beneficial as any established alternatives.
5. There is insufficient information or inconclusive scientific evidence that, when used in a non-investigational setting, the service, procedure or supply has a beneficial effect on health outcomes or is as beneficial as any established alternatives.

The American Medical Association (AMA) develops Current Procedural Terminology (CPT) Category III codes to allow for data collection concerning the use of "emerging technology, services, and procedures." The creation of a CPT Category III code by the AMA "neither implies nor endorses clinical efficacy, safety or the applicability to clinical practice. Because of the specific purpose these Category III codes serve, ConnectiCare, Inc. will consider the item, service, or procedure represented by these codes to be not medically necessary.

*Note: Once a Category III CPT code is replaced by a Category I CPT code, the item, service, or procedure should not be presumed to be medically necessary.*

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 referred 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.

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The following CPT/HCPCS procedure codes are investigational and unproven and are therefore not covered.

## Experimental & Noncovered Investigational by CPT Code (Commercial Plans)

19105	20560	20561	20983	22526	22527	28890	30468	33274	33275	33289	33340
33542	33548	34839	34841	34842	34843	34844	34845	34846	34847	34848	36473
36474	37188	41512	41530	43206	43210	43252	43257	43284	43285	46707	53451
53452	53453	53454	53855	54240	62287	64575	64625	64910	64911	69705	69706
76120	76125	81204	81560	82777	83006	83987	84066	84112	84145	86152	86153
88375	91112	91113	91132	91133	92145	92227	92512	93050	93702	93740	93895
95012	95803	96002	96004	96931	96932	96933	96934	96935	96936	97026	97610
0014M	0015M	0016M	0018M	0071T	0072T	0075T	0076T	0095T	0101T	0102T	0106T
0107T	0108T	0109T	0110T	0163T	0164T	0165T	0174T	0175T	0198T	0200T	0201T
0202T	0203U	0204U	0205U	0206U	0207T	0207U	0208T	0208U	0209T	0209U	0210T
0210U	0211T	0211U	0212T	0212U	0213U	0214T	0214U	0215T	0215U	0216U	0217T
0217U	0218T	0218U	0219T	0219U	0220T	0220U	0221T	0221U	0222T	0222U	0232T
0234T	0235T	0236T	0237T	0238T	0243U	0247U	0248U	0249U	0251U	0253T	0255U
0256U	0257U	0258U	0259U	0261U	0263T	0263U	0264T	0265T	0266T	0267T	0268T
0269T	0270T	0271T	0272T	0273T	0274T	0275T	0275U	0278T	0279U	0280U	0281U
0283U	0284U	0295U	0303U	0304U	0305U	0312T	0313T	0314T	0315T	0316T	0317T
0329T	0330T	0331T	0332T	0333T	0335T	0338T	0339T	0342T	0347T	0348T	0349T
0350T	0351T	0352T	0353T	0354T	0358T	0362T	0373T	0375T	0378T	0379T	0398T
0403T	0404T	0408T	0409T	0410T	0411T	0412T	0413T	0414T	0415T	0416T	0417T
0418T	0419T	0420T	0422T	0424T	0425T	0426T	0427T	0428T	0429T	0430T	0431T
0432T	0433T	0434T	0435T	0436T	0437T	0440T	0442T	0443T	0444T	0445T	0450T
0464T	0465T	0469T	0470T	0471T	0472T	0473T	0474T	0475T	0476T	0477T	0478T
0479T	0480T	0481T	0485T	0486T	0487T	0488T	0489T	0490T	0491T	0492T	0493T
0494T	0495T	0496T	0497T	0498T	0499T	0500T	0506T	0507T	0508T	0510T	0511T
0512T	0513T	0514T	0515T	0516T	0517T	0518T	0519T	0520T	0521T	0522T	0523T
0524T	0525T	0526T	0527T	0528T	0529T	0530T	0531T	0532T	0533T	0534T	0535T
0536T	0541T	0542T	0545T	0546T	0547T	0552T	0554T	0555T	0556T	0557T	0558T
0559T	0560T	0561T	0562T	0621T	0622T	0623T	0624T	0625T	0626T	0627T	0628T
0629T	0630T	0631T	0632T	0633T	0634T	0635T	0636T	0637T	0638T	0639T	0640T
0641T	0642T	0643T	0644T	0645T	0646T	0647T	0648T	0649T	0651T	0655T	0656T
0657T	0658T	0659T	0660T	0661T	0664T	0665T	0666T	0667T	0668T	0669T	0670T
0672T	0673T	0674T	0675T	0676T	0677T	0678T	0679T	0680T	0681T	0682T	0683T
0684T	0685T	0686T	0687T	0688T	0689T	0690T	0691T	0692T	0693T	0694T	0695T
0696T	0697T	0698T	0700T	0701T	0702T	0703T	0704T	0705T	0706T	0707T	0708T
0709T	0710T	0711T	0712T	0713T	A4337	A4563	A4575	A4638	A4639	A6000	C1833
C9771	E0218	E0221	E0231	E0232	E0236	E0761	E0762	E2120	G0252	G0255	G0281
G0282	G0295	G0329	G0341	G0342	G0343	G0428	G0460	G9143	G9147	K1006	K1007
K1009	K1016	K1017	K1020	L8605	L8608	Q1004	Q1005	Q4113	Q4114	Q4125	Q4130
Q4139	Q4142	Q4143	Q4145	Q4148	Q4149	Q4150	Q4155	Q4156	Q4162	Q4167	Q4171

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Experimental & Noncovered Investigational by CPT Code (Commercial Plans)											
Q4176	Q4177	Q4178	Q4179	Q4180	Q4181	Q4183	Q4184	Q4185	Q4188	Q4189	Q4190
Q4191	Q4193	Q4194	Q4198	Q4199	Q4200	Q4201	Q4202	Q4203	Q4204	Q4251	Q4252
Q4253	S0800	S1030	S1031	S2117	S2140	S2300	S2348	S3650	S3722	S3900	S8080
S8130	S8131	S8930	S9055	S9090							

Note: 'No specific code available' indicates an "unlisted code" or "miscellaneous code."

**The following CPT/HCPCS procedure codes are investigational and unproven and are therefore not covered.**

Experimental & Noncovered Investigational by CPT Code (Medicare Plans)													
20560	20561	22526	22527	30468	33542	33548	34839	34841	34842	34843	34844	34845	34846
34847	34848	43257	43284	53451	53452	53453	53454	62287	64625	69705	69706	75571	81105
81106	81107	81108	81109	81110	81111	81112	81173	81174	81200	81204	81205	81227	81230
81231	81232	81234	81239	81240	81241	81242	81243	81244	81247	81250	81251	81254	81255
81260	81271	81274	81284	81285	81286	81289	81290	81291	81324	81327	81328	81329	81330
81331	81336	81337	81346	81361	81362	81363	81364	81410	81411	81415	81416	81417	81420
81425	81426	81427	81430	81431	81432	81433	81434	81439	81440	81442	81443	81448	81455
81460	81465	81470	81471	81493	81504	81525	81535	81536	81540	81560	82777	83006	84066
86152	86153	89253	91113	92145	92227	93895	94014	94015	94016	97026	0007M	0014M	0015M
0018M	0071T	0072T	0075T	0076T	0095T	0098T	0101T	0102T	0106T	0107T	0108T	0109T	0110T
0163T	0164T	0165T	0174T	0175T	0198T	0200T	0201T	0202T	0206U	0207T	0207U	0208T	0208U
0209T	0210T	0210U	0211T	0212T	0213T	0214T	0215T	0216T	0217T	0218T	0219T	0220T	0221T
0222T	0232T	0234T	0235T	0236T	0237T	0238T	0243U	0247U	0248U	0249U	0251U	0253T	0255U
0256U	0257U	0259U	0261U	0263T	0263U	0264T	0265T	0266T	0267T	0268T	0269T	0270T	0271T
0272T	0273T	0274T	0275T	0275U	0278T	0279U	0280U	0281U	0283U	0284U	0295U	0303U	0304U
0305U	0312T	0313T	0314T	0315T	0316T	0317T	0329T	0330T	0331T	0332T	0333T	0335T	0338T
0339T	0342T	0345T	0347T	0348T	0349T	0350T	0351T	0352T	0353T	0354T	0358T	0362T	0373T
0378T	0379T	0394T	0395T	0402T	0403T	0404T	0408T	0409T	0410T	0411T	0412T	0413T	0414T
0415T	0416T	0417T	0418T	0419T	0420T	0422T	0424T	0425T	0426T	0427T	0428T	0429T	0430T
0431T	0432T	0433T	0434T	0435T	0436T	0437T	0440T	0442T	0443T	0444T	0445T	0450T	0464T
0465T	0469T	0470T	0471T	0473T	0474T	0475T	0476T	0477T	0478T	0479T	0480T	0481T	0483T
0484T	0485T	0486T	0487T	0488T	0489T	0490T	0491T	0492T	0493T	0494T	0495T	0496T	0497T
0498T	0499T	0500T	0506T	0507T	0508T	0510T	0511T	0512T	0513T	0514T	0523T	0524T	0525T
0526T	0527T	0528T	0529T	0530T	0531T	0532T	0533T	0534T	0535T	0536T	0541T	0542T	0543T
0544T	0545T	0546T	0547T	0552T	0553T	0554T	0559T	0560T	0561T	0562T	0563T	0564T	0565T
0566T	0567T	0568T	0569T	0570T	0571T	0572T	0573T	0574T	0575T	0576T	0577T	0578T	0579T
0580T	0581T	0582T	0583T	0587T	0588T	0589T	0590T	0591T	0592T	0593T	0621T	0622T	0623T
0624T	0625T	0626T	0627T	0628T	0629T	0630T	0631T	0632T	0633T	0634T	0635T	0636T	0637T
0638T	0639T	0640T	0641T	0642T	0643T	0644T	0645T	0646T	0647T	0648T	0649T	0651T	0655T
0656T	0657T	0658T	0659T	0660T	0661T	0664T	0665T	0666T	0667T	0668T	0669T	0670T	0672T
0673T	0674T	0675T	0676T	0677T	0678T	0679T	0680T	0681T	0682T	0683T	0684T	0685T	0686T
0687T	0688T	0689T	0690T	0691T	0692T	0693T	0694T	0695T	0696T	0697T	0698T	0700T	0701T

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Experimental & Noncovered Investigational by CPT Code (Medicare Plans)													
0702T	0703T	0704T	0705T	0706T	0707T	0708T	0709T	0710T	0711T	0712T	0713T	A4337	A4575
A4638	A4639	A6000	C9771	E0218	E0221	E0231	E0232	E0236	E0762	E2120	G0252	G0255	G0282
G0295	G0341	G0342	G0343	G0428	G9147	K1006	K1007	K1009	K1016	K1017	K1020	L8605	L8608
M0076	Q0515	Q1004	Q1005	Q4113	Q4114	Q4125	Q4130	Q4139	Q4142	Q4143	Q4145	Q4148	Q4149
Q4150	Q4155	Q4156	Q4162	Q4167	Q4171	Q4176	Q4177	Q4178	Q4179	Q4180	Q4181	Q4183	Q4184
Q4185	Q4188	Q4189	Q4190	Q4191	Q4193	Q4194	Q4198	Q4199	Q4200	Q4201	Q4202	Q4203	Q4204
Q4251	Q4252	Q4253	S0800	S1030	S1031	S2117	S2140	S2300	S2348	S3650	S3722	S3800	S3852
S3900	S8030	S8037	S8080	S8092	S8130	S8131	S8930	S8948	S9090	S9558			

## Revision history

DATE	REVISION
1/11/2022	<ul style="list-style-type: none"> <li>Removed Codes from policy                             <ul style="list-style-type: none"> <li><u>Commercial</u>: 0054T, 0055T and 20985</li> <li><u>Medicare</u>: 0054T and 0055T</li> </ul> </li> </ul>
12/21/2021	<ul style="list-style-type: none"> <li>Added new CPT Codes effective <b>1/01/2022</b>:  <u>Medicare</u>: 0672T, 0673T, 0674T, 0675T, 0676T, 0677T, 0678T, 0679T, 0680T, 0681T, 0682T, 0683T, 0684T, 0685T, 0686T, 0687T, 0688T, 0689T, 0690T, 0691T, 0692T, 0693T, 0694T, 0695T, 0696T, 0697T, 0698T, 0700T, 0701T, 0702T, 0703T, 0704T, 0705T, 0706T, 0707T, 0708T, 0709T, 0710T, 0711T, 0712T, 0713T, 53451, 53452, 53453, 53454, 81560, 91113, Q4199, 0295U, 0303U, 0304U &amp; 0305U  <u>Commercial</u>: 0672T, 0673T, 0674T, 0675T, 0676T, 0677T, 0678T, 0679T, 0680T, 0681T, 0682T, 0683T, 0684T, 0685T, 0686T, 0687T, 0688T, 0689T, 0690T, 0691T, 0692T, 0693T, 0694T, 0695T, 0696T, 0697T, 0698T, 0700T, 0701T, 0702T, 0703T, 0704T, 0705T, 0706T, 0707T, 0708T, 0709T, 0710T, 0711T, 0712T, 0713T, 53451, 53452, 53453, 53454, 81560, 91113, C1833, Q4199, 0295U, 0303U, 0304U &amp; 0305U                             <ul style="list-style-type: none"> <li><i>Removed Deleted Codes Effective 1/01/2022</i>: 0355T, 0356T, 0376T, 0423T, 0451T, 0452T, 0453T, 0454T, 0455T, 0456T, 0457T, 0458T, 0459T, 0460T, 0461T, 0462T, 0463T, 0466T, 0467T, 0468T, 0548T, 0549T, 0550T &amp; 0551T</li> </ul> </li> </ul>
10/22/2021	<ul style="list-style-type: none"> <li>Removed 0505T from both Commercial and Medicare effective 8/7/2021</li> </ul>
9/29/2021	<ul style="list-style-type: none"> <li>Added new CPT Codes effective 10/01/2021:  <u>Medicare</u>: 0018M, 0255U, 0256U, 0257U, 0259U, 0261U, 0263U, 0275U, 0279U, 0280U, 0281U, 0283U, 0284U, Q4251, Q4252 &amp; Q4253  <u>Commercial</u>: 0018M, 0255U, 0256U, 0257U, 0258U, 0259U, 0261U, 0263U, 0275U, 0279U, 0280U, 0281U, 0283U, 0284U, Q4251, Q4252 &amp; Q4253                             </li> </ul>
6/25/2021	<ul style="list-style-type: none"> <li>Added new CPT Codes effective 7/01/2021: 0248U, 0249U, 0251U, 0640T, 0641T, 0642T, 0643T, 0644T, 0645T, 0646T, 0647T, 0648T, 0649T, 0651T, 0655T, 0656T, 0657T, 0658T, 0659T, 0664T, 0665T, 0666T, 0667T, 0668T, 0669T, 0670T, 0660T, 0661T for both Commercial &amp; Medicare</li> </ul>

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DATE	REVISION
3/24/2021	<ul style="list-style-type: none"> <li>Added new CPT Codes effective 4/1/2021; 0243U, 0247U, K1016, K1017 &amp; K1020 for both Commercial &amp; Medicare</li> <li>Removed deleted CPT Codes effective 4/01/2021; K1010, K1011 &amp; K1012 from Commercial</li> </ul> <p><b>Effective 5/1/2021:</b></p> <ul style="list-style-type: none"> <li>Removed 0421T from Commercial and Medicare LOB</li> <li>Removed 0042T from Medicare LOB</li> </ul>
03/02/2021	<ul style="list-style-type: none"> <li>Removed CPT codes 37187, 37188 for Commercial LOB</li> </ul>
12/31/2020	<ul style="list-style-type: none"> <li>Added new CPT Codes effective 1/01/2021: 0621T, 0622T, 0623T, 0624T, 0625T, 0626T, 0627T, 0628T, 0629T, 0630T, 0631T, 0632T, 0633T, 0634T, 0635T, 0636T, 0637T, 0638T, 0639T, 30468, 69705, 69706 &amp; C9771 for both Commercial &amp; Medicare</li> <li>Removed Deleted Codes: 0058T, 0085T, 0111T, 0126T, 0228T, 0229T, 0230T, 0231T, 0381T, 0382T, 0383T, 0384T, 0385T, 0386T, 0396T, 0400T, 0401T, 0405T</li> </ul>
10/2020	<ul style="list-style-type: none"> <li>Added new CPT Codes effective 10/1/2020: 0014M, 0015M, 0206U, 0207U, 0210U, K1006, K1007 &amp; K1009 for both Commercial &amp; Medicare.</li> <li>Added new CPT Codes effective 10/1/2020: K1010, K1011 &amp; K1012 Commercial <i>only</i></li> </ul>
07/2020	<ul style="list-style-type: none"> <li>Removed CPT codes 0345T, 0483T, 0484T, 0543T &amp; 0544T-Commercial only</li> </ul>
02/2020	<ul style="list-style-type: none"> <li>Added CPT codes 64625, 20560 &amp; 20561 for both commercial &amp; Medicare</li> </ul>
11/2019	<ul style="list-style-type: none"> <li>Title changed from Medical Necessity Guidelines for noncovered investigational services to Medical Necessity Guidelines: Experimental, Investigational or Unproven Services to coincide with definitional enhancements.</li> </ul>
04/2019	<ul style="list-style-type: none"> <li>New Policy. Effective date 1/1/2020</li> </ul>