

MEDICAL POLICY

POLICY TITLE	EXPERIMENTAL AND INVESTIGATIONAL PROCEDURES
POLICY NUMBER	MP- 4.002

Original Issue Date (Created):	8/9/2002
Most Recent Review Date (Revised):	7/15/2019
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[POLICY RATIONALE](#)
[DISCLAIMER](#)
[POLICY HISTORY](#)

[PRODUCT VARIATIONS](#)
[DEFINITIONS](#)
[CODING INFORMATION](#)

[DESCRIPTION/BACKGROUND](#)
[BENEFIT VARIATIONS](#)
[REFERENCES](#)

I. POLICY

A service or supply, including, but not limited to, a drug, treatment, device, or procedure is considered **experimental or investigational** if any of the following criteria are met:

- It cannot be lawfully marketed without the approval of the Food and Drug Administration (FDA) and final approval is not granted at the time of its use or proposed use;
- It is the subject of a current investigational new drug or new device application on file with the FDA;
- The predominant opinion among experts as expressed in medical literature is that usage should be largely confined to research settings;
- The predominant opinion among experts as expressed in medical literature is that further research is needed in order to define safety, toxicity, effectiveness or effectiveness compared with other approved alternatives; or
- It is not investigational in itself, but would not be medically necessary except for its use with a drug, device, treatment or procedure that is investigational or experimental.

When determining whether a drug, treatment, device, or procedure is experimental or investigational, the following information may be considered:

- The member’s medical record;
- The protocol(s) pursuant to which the treatment is to be delivered;
- Any consent document the patient has signed or will be asked to sign, in order to undergo the procedure;
- The referenced medical or scientific literature regarding the procedure at issue as applied to the injury or illness at issue;
- Regulations and other official actions and publications issued by the federal government; and

MEDICAL POLICY

POLICY TITLE	EXPERIMENTAL AND INVESTIGATIONAL PROCEDURES
POLICY NUMBER	MP- 4.002

- The opinion of a third party medical expert in the field, obtained by Capital BlueCross, with respect to whether a treatment or procedure is experimental or investigational.

Cross-references:

- MP- 2.010** Clinical Trials and Expanded Access Services
- MP- 2.103** Off-Label Use of Medications

II. PRODUCT VARIATIONS

[TOP](#)

This policy is only applicable to certain programs and products administered by Capital BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

III. DESCRIPTION/BACKGROUND

[TOP](#)

This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

IV. RATIONALE

[TOP](#)

NA

V. DEFINITIONS

[TOP](#)

NA

VI. BENEFIT VARIATIONS

[TOP](#)

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

[TOP](#)

Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any

MEDICAL POLICY

POLICY TITLE	EXPERIMENTAL AND INVESTIGATIONAL PROCEDURES
POLICY NUMBER	MP- 4.002

medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

[TOP](#)

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

The following procedure codes are denied as experimental/investigational based on the guidelines of this policy:

CPT Codes®								
15773	15774	19294	33274	33275	34717	34718	55874	62380
78350	78351	90619	90697	91132	91133	0006M	0007M	0012M
0013M	0015M	0098T	0174T	0175T	0184T	0208T	0209T	0210T
0211T	0212T	0234T	0235T	0236T	0237T	0238T	0278T	0308T
0329T	0338T	0339T	0347T	0348T	0349T	0350T	0351T	0352T
0353T	0354T	0356T	0358T	0378T	0379T	0403T	0408T	0409T
0410T	0411T	0412T	0413T	0414T	0415T	0416T	0417T	0421T
0422T	0423T	0424T	0425T	0426T	0427T	0428T	0429T	0430T
0431T	0432T	0433T	0434T	0435T	0436T	0437T	0439T	0440T
0442T	0443T	0444T	0445T	0469T	0475T	0476T	0477T	0478T
0479T	0480T	0481T	0484T	0489T	0490T	0494T	0495T	0496T
0499T	0500T	0505T	0506T	0508T	0509T	0514T	0523T	0525T
0526T	0527T	0528T	0529T	0530T	0531T	0532T	0533T	0534T
0535T	0536T	0541T	0547T	0542T	0543T	0545T	0548T	0549T
0550T	0551T	0553T	0554T	0555T	0556T	0557T	0558T	0559T
0560T	0561T	0562T	0565T	0566T	0567T	0568T	0569T	0570T
0571T	0572T	0573T	0574T	0575T	0576T	0577T	0578T	0579T
0580T	0583T	0596T	0597T	0598T	0599T	0602T	0603T	0613T
0616T	0619T	0620T	0621T	0622T	0627T	0628T	0629T	0630T
0631T	0632T	0635T	0636T	0637T	0638T	0639T	0025U	0055U
0059U	0063U	0064U	0065U	0066U	0067U	0069U	0077U	0079U
0083U	0085U	0086U	0087U	0088U	0092U	0093U	0095U	0096U
0097U	0098U	0099U	0100U	0105U	0106U	0107U	0108U	0109U
0110U	0112U	0114U	0115U	0116U	0117U	0118U	0119U	0120U
0121U	0122U	0123U	0139U	0140U	0141U	0142U	0143U	0144U

MEDICAL POLICY

POLICY TITLE	EXPERIMENTAL AND INVESTIGATIONAL PROCEDURES
POLICY NUMBER	MP- 4.002

0145U	0146U	0147U	0148U	0149U	0150U	0151U	0152U	0156U
0164U	0202U	0210U	0214U	0215U	0216U	0217U	0218U	0220U
0221U	30468	81514	92517	92518	92519			

Current Procedural Terminology (CPT) copyrighted by American Medical Association. All Rights Reserved.

HCPCS Code	Description
A4563	Rectal control system for vaginal insertion, for long term use, includes pump and all supplies and accessories, any type each
A9586	Florbetapir F18, diagnostic, per study dose, up to 10 millicuries
B4105	In-line cartridge containing digestive enzyme(s) for enteral feeding, each
C1748	Endoscope, single-use (i.e. disposable), upper gi, imaging/illumination device (insertable)
C1749	Endoscope, retrograde imaging/illumination colonoscope device (implantable)
C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads
C1824	Generator, cardiac contractility modulation (implantable)
C1839	Iris prosthesis
C1849	Skin substitute, synthetic, resorbable, per square centimeter
C9122	Mometasone furoate sinus implant, 10 micrograms (sinuva)
C9752	Destruction of intraosseous basivertebral nerve, first two vertebral bodies, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum
C9753	Destruction of intraosseous basivertebral nerve, each additional vertebral body, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum (list separately in addition to code for primary procedure)
C9758	Blinded procedure for NYHA Class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, transesophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study
C9760	Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study
C9762	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with strain imaging
C9763	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with stress imaging
C9764	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed

POLICY TITLE	EXPERIMENTAL AND INVESTIGATIONAL PROCEDURES
POLICY NUMBER	MP- 4.002

C9765	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
C9766	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed
C9767	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed
C9768	Endoscopic ultrasound-guided direct measurement of hepatic portosystemic pressure gradient by any method (list separately in addition to code for primary procedure)
C9772	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed
C9773	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed
C9774	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed
C9775	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed
E0350	Control unit for electronic bowel irrigation/evacuation system
E0352	Disposable pack (water reservoir bag, speculum, valving mechanism, and collection bag/box) for use with the electronic bowel irrigation/evacuation system
G0186	Destruction of localized lesion of choroid (for example, choroidal neovascularization); photocoagulation, feeder vessel technique (one or more sessions)
G0276	Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial
G0428	Collagen meniscus implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)
G9147	Outpatient Intravenous Insulin Treatment (OIVIT) either pulsatile or continuous, by any means, guided by the results of measurements for: respiratory quotient; and/or, urine urea nitrogen (UUN); and/or, arterial, venous or capillary glucose; and/or potassium concentration
K1007	Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors.
K1009	Speech volume modulation system, any type, including all components and accessories.
K1010	Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each.

MEDICAL POLICY

POLICY TITLE	EXPERIMENTAL AND INVESTIGATIONAL PROCEDURES
POLICY NUMBER	MP- 4.002

K1011	Activation device for intraurethral drainage device with valve, replacement only, each.
K1012	Charger and base station for intraurethral activation device, replacement only.
L8701	Elbow, wrist, hand device, powered, with single or double upright(s), any type joint(s), includes microprocessor, sensors, all components and accessories.
L8702	Elbow, wrist, hand, finger device, powered, with single or double upright(s), any type joint(s), includes microprocessor, sensors, all components and accessories.
P2031	Hair analysis (excluding arsenic)
S2103	Adrenal tissue transplant to brain
S2107	Adoptive immunotherapy i.e. development of specific antitumor reactivity (e.g., tumor-infiltrating lymphocyte therapy) per course of treatment
S2400	Repair, congenital diaphragmatic hernia in the fetus using temporary tracheal occlusion, procedure performed in utero.
V2524	Contact lens, hydrophilic, spherical, photochromic additive, per lens.

IX. REFERENCES

[TOP](#)

1. *BCBSA TEC Evaluation Center Criteria. 12/16/16 [Website]:*
http://bluewebportal.bcbs.com/programs/center-clinical-effectiveness/-/asset_publisher/jaTkpw6RxA/content/tec-assessments Accessed July 15, 2019.
2. *Centers for Medicare and Medicaid Services (CMS) Medicare Benefit Policy Manual. Publication 100-02. Chapter 14. Medical Devices. Rev. 1. Effective 10/01/03 [Website]:*
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-Ioms-Items/Cms012673.html> Accessed July 15, 2019.
3. *Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) 20.33 Transcatheter Mitral Valve Repair (TMVR). Effective 08/07/14. CMS [Website]:* <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=363&ncdver=1&bc=AAAAgAAAAAAAAA%3d%3d&> Accessed July 15, 2019.
4. *Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) 40.7 Outpatient Intravenous Insulin Treatment. Effective 12/23/09. CMS [Website]:*
<https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=334&ncdver=1&bc=AAAAgAAAAAAAAA%3d%3d&> Accessed July 15, 2019.
5. *Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) 220.6.20 Beta Amyloid Positron Tomography in Dementia and Neurodegenerative Disease. Effective 09/07/13.*
6. *Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) 220.6.13 FDG PET for Dementia and Neurodegenerative Diseases.*
<https://www.cms.gov/medicare-coverage-database/details/ncd->

POLICY TITLE	EXPERIMENTAL AND INVESTIGATIONAL PROCEDURES
POLICY NUMBER	MP- 4.002

[details.aspx?NCDId=288&ncdver=3&DocID=220.6.13&SearchType=Advanced&bc=IAA AABAAAAAAAA%3d%3d&](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?NCDId=288&ncdver=3&DocID=220.6.13&SearchType=Advanced&bc=IAA AABAAAAAAAA%3d%3d&) Effective 04/03/09. Accessed July 15, 2019.

- Novitas Solutions. Local Coverage Determination (LCD) L35094 Services That Are Not Reasonable and Necessary. Effective 01/01/2018 [Website]: <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?Date=10%2F29%2F2015&SearchType=Advanced&LCDId=35094&ContrId=323&DocID=L35094&bc=KAAAAAgAAAAAAAA%3D%3D> Accessed July 15, 2019

X. POLICY HISTORY

[TOP](#)

MP 4.002	CAC 6/29/04
	CAC 10/26/04
	CAC 10/25/05
	CAC 11/29/05
	CAC 11/28/06
	CAC 11/27/07
	CAC 9/29/09 Consensus review
	CAC 9/28/10 Consensus review
	CAC 10/25/11 Consensus review. FEP PPO variation added for new definition of experimental/investigational.
	CAC 10/30/12 Consensus review. References updated, but no changes to policy statements. Deleted product variations for all plans – refer to the COC for specific benefit information.
	CAC 11/26/13 Consensus review
	CAC 11/25/14 Consensus review. References updated. No changes to the policy statements.
	CAC 11/24/15 Consensus review. References updated. No change to policy statements. Coding reviewed.
	CAC 9/27/16 Consensus review. References updated. No changes to the policy statements. Variations reformatted.
	CAC 5/23/17 Minor revision. Policy revised for clarification. References updated. Coding added, including new codes for 1/1/18
	1/19/18 Administrative update. End dated deleted codes 0004U & 0015U; effective 1/1/18. Added new codes 0501T-0504T, 0025U & 19294; effective 1/1/18. Corrected duplicate typos.
2/7/18 Consensus review. References updated. No changes to the policy statements. Administrative Coding update: 0501T-0504T removed; See NIA guidelines for management.	
3/27/18 Administrative update. Added codes G0186, S2400, 78350, and 78351.	

POLICY TITLE	EXPERIMENTAL AND INVESTIGATIONAL PROCEDURES
POLICY NUMBER	MP- 4.002

	4/1/18 Administrative update. Removed code C9359. Added code 0039U; effective 4/1/2018.
	6/1/18 Administrative update. Removed code 90750 since now FDA approved for age 50 years and older.
	7/1/18 Administrative update. Removed code 0345T since now will be medically necessary on MP 1.153 and 0482T, which is managed by NIA. New codes 0505T, 0506T, 0507T, 0050U, 0056U, 0059U, 0061U and Q9994 added effective 7/1/18.
	7/31/18 Administrative update. 0402T removed from policy, G0428 added. S2107 added.
	10/1/2018 Administrative update. Removed deleted code and added new codes effective 10/1/18.
	11/1/2018 Administrative update. Removed 0050U & 0056U to correspond with new policy posting 11/1/18. 0508T was added to correspond with BCBSA stance & CBC stance.
	12/1/2018 Administrative update. Removed C9747 & C9748 to correspond with new policy posting that speaks to these codes. See MP 4.043.
	1/1/2019 Administrative update. Removed deleted codes. Added new codes 0509T, 0512T-0514T, 0523T-0542T, 33274-33275, 83722, A4563, B4105. Also added existing codes 0098T, 0357T, 62380, 89337, and G0276 to correspond with TurningPoint changes 1/1/19 and retirement of MP 7.002 of 1/1/19.
	1/4/2019 Administrative update. Added new codes 0082U, 0083U, C1823, C9752, C9753, L8701, L8702 effective 1/1/19.
	2/1/2019 Administrative update. Added codes from retired lab policies with codes not to be managed by Avalon 0041U, 0042U, 0043U, 0044U, 0051U, 0052U, 0055U, 0012M, 0013M, P2031, S3652
	5/10/2019 Administrative update. Adding code 0490T to correspond with update on MP 9.053 effective 7/1/19. Added new codes effective 7/1/19 – 0085U, 0086U, 0087U, 0088U, 0092U. 0093U, 0095U, 0096U, 0097U, 0098U, 0099U, 0100U, 0543T, 0545T, 0547T, 0548T, 0549T, 0550T, 0551T, 0553T, 0554T, 0555T, 0556T, 0557T, 0558T, 0559T, 0560T, 0561T, 0562T, and 90619
	7/15/19 Administrative update. Removed many codes that were no longer active. Removed codes to be managed by Avalon, see Laboratory Services policies for current criteria related to 0008U, 0011U, 0012M, 0013M, 0039U, 0041U, 0042U, 0043U, 0044U, 0054U, 0062U, 0068U, 0082U.
	10/1/19 Coding update. Coding reviewed. Removed codes that were no longer active or listed on other policies. New codes effective 10/1/19 added.

POLICY TITLE	EXPERIMENTAL AND INVESTIGATIONAL PROCEDURES
POLICY NUMBER	MP- 4.002

	1/1/2020 Coding update. New 2020 codes added, deleted codes removed, and revised descriptions as applicable. Also moving codes 0491T, 0492T, 0493T, 0512T, and 0513T from MP 4.002 to MP 4.028 effective 1/1/2020.
	3/1/2020 Coding update. Added 0012M and 0013M as investigational.
	4/1/2020 Coding update. New code 0164U added for IBS-Detex.
	5/29/2020 Administrative update. Added new codes effective 7/1/2020: C1748, C1849, C9059, C9061, C9063, C9122, C9760, C9762, C9763, C9764, C9765, C9766, C9767, 0596T, 0597T, 0598T, 0599T, 0602T, 0603T, 0613T, 0616T, 0619T
	9/8/2020 Administrative update. Deleted Codes: C9059, C9061, C9063. Added codes: 0015M, 0210U, 0214U, 0215U, 0216U, 0217U, 0218U, 0220U, 0221U, 0222U, C9768, K1007, K1009, K1010, K1011, K1012
	11/30/2020 Administrative update. Added new codes 0623T, 0624T, 0625T, 0626T, 0633T, 0634T, 0635T, 0636T, 0637T, 0638T. Effective 1/1/21.
	12/14/2020 Administrative update. Added new codes C9772, C9773, C9774 and C9775. Revised code C9760. Deleted codes Deleted codes 0124U, 0125U, 0126U, 0127U, 0128U, 0405T and C9745. Effective 1/1/2021.

[Top](#)

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