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):	**1/9/2019**
Effective Date:	**2/1/2019**

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
- The opinion of a third party medical expert in the field, obtained by Capital, 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

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

III. DESCRIPTION/BACKGROUND

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This policy describes the circumstances under which a service is considered experimental/investigational. Claims submitted for the services will be denied as experimental/investigational based on the criteria/guidelines found above in the policy section.

IV. RATIONALE

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NA

V. DEFINITIONS

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NA

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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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 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. 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

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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®								
19294	33274	33275	55874	62380	78350	78351	83772	89337
90697	90739	91132	91133	0006M	0007M	0012M	0013M	0098T
0174T	0175T	0178T	0179T	0180T	0184T	0202T	0205T	0206T
0208T	0209T	0210T	0211T	0212T	0219T	0220T	0221T	0222T
0234T	0235T	0236T	0237T	0238T	0249T	0254T	0255T	0278T
0302T	0303T	0304T	0305T	0306T	0307T	0308T	0309T	0329T
0338T	0339T	0341T	0345T	0347T	0348T	0349T	0350T	0351T
0352T	0353T	0354T	0356T	0357T	0358T	0378T	0379T	0381T
0382T	0383T	0384T	0385T	0386T	0399T	0403T	0404T	0405T
0408T	0409T	0410T	0411T	0412T	0413T	0414T	0415T	0416T
0417T	0418T	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	0483T	0484T	0485T
0486T	0487T	0489T	0491T	0492T	0493T	0494T	0495T	0496T
0497T	0498T	0499T	0500T	0505T	0506T	0507T	0508T	0509T
0512T	0513T	0514T	0523T	0525T	0526T	0527T	0528T	0529T
0530T	0531T	0532T	0533T	0534T	0535T	0536T	0541T	0542T
0002U	0006U	0008U	0010U	0011U	0025U	0039U	0041U	0042U
0043U	0044U	0051U	0052U	0055U	0059U	0061U	0062U	0063U
0064U	0065U	0066U	0067U	0068U	0069U	0077U	0079U	0082U
0083U								

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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
C1749	Endoscope, retrograde imaging/illumination colonoscope device (implantable)
C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads
C9745	Nasal endoscopy, surgical; balloon dilation of eustachian tube
C9746	Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed and/or fluoroscopy, when performed
C9750	Insertion or removal and replacement of intracardiac ischemia monitoring system including imaging supervision and interpretation and peri-operative interrogation and programming; complete system (includes device and electrode)
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)
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
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
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

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
S3652	Saliva test, hormone level; to assess preterm labor risk

IX. REFERENCES

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BCBSA TEC Evaluation Center Criteria. 12/16/16 [Website]: http://bluewebportal.bcbs.com/programs/center-clinical-effectiveness/-/asset_publisher/jaTkpwa6RxsA/content/tec-assessments Accessed February 7, 2018.

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 February 7, 2018.

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 February 7, 2018.

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 February 7, 2018.

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. Accessed February 7, 2018.

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-details.aspx?NCDId=288&ncdver=3&DocID=220.6.13&SearchType=Advanced&bc=IAAAABAAAAAAAA%3d%3d& Effective 04/03/09. Accessed February 7, 2018.

Durable Medical Equipment Regional Carrier (DME MAC JA) Region JA Noridian Healthcare Solutions, LLC Local Coverage Determination (LCD) L36267 Bowel

*Management Devices. Effective 01/01/17. [Website]: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36267&ContrId=139&ver=17&ContrVer=2&CntrctrSelected=139*2&Cntrctr=139&name=Noridian+Healthcare+Solutions%2c+LLC+(19003%2c+DME+MAC)&s=6&DocType=Active&bc=AggAAAQAAAAAAA%3d%3d& Accessed February 7, 2018.*

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=KAAAAAgAAAAAAA%3D%3D Accessed February 7, 2018.

Novitas Solutions. Local Coverage Article (LCA) A53134 NCD Coding Article for Positron Emission Tomography (PET) scans Used for Non-Oncologic Conditions. 01/01/18 [Website]: https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=53134&ver=43&Date=02%2f07%2f2018&SearchType=Advanced&ContrId=&DocID=A53134&bc=JAAAABgAAAAA&Accessed February 7, 2018.

X. POLICY HISTORY

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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
Admin Update 1/19/18: 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. References updated. No changes to the policy statements. **Admin Coding Update:** 0501T-0504T removed; See NIA guidelines for management.
3/27/18 Admin update: Added codes G0186, S2400, 78350, and 78351.
4/1/18 Admin update: Removed code C9359. Added code 0039U; effective 4/1/2018.
6/1/18 Admin update: Removed code 90750 since now FDA approved for age 50 years and older.
7/1/18 Admin 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 Admin update: 0402T removed from policy, G0428 added. S2107 added.
10/1/2018 Admin Update: Removed deleted code and added new codes effective 10/1/18.
11/1/2018 Admin 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 Admin Update: Removed C9747 & C9748 to correspond with new policy posting that speaks to these codes. See MP 4.043.
1/1/2019 Admin 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 Admin Update: Added new codes 0082U, 0083U, C1823, C9752, C9753, L8701, L8702 effective 1/1/19.
2/1/2019 Admin 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

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