

MEDICAL POLICY

POLICY TITLE	EXPERIMENTAL AND INVESTIGATIONAL PROCEDURES
POLICY NUMBER	MP 4.002
Effective Date:	4/1/2024

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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 Blue Cross, 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

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II. PRODUCT VARIATIONS

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

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

<https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>.

III. DESCRIPTION/BACKGROUND

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

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 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 Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross'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. 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 Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

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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:

Procedure Codes								
30468	30469	53451	53452	53453	53454	77089	77090	77091
77092	81560	83529	87467	90584	91132	91133	92517	92518
92519	0015M	0019M	0025U	0061U	0063U	0066U	0067U	0077U
0088U	0095U	0105U	0106U	0107U	0108U	0109U	0110U	0112U
0114U	0115U	0116U	0117U	0119U	0121U	0122U	0123U	0164U
0174T	0175T	0202U	0220U	0221U	0234T	0235T	0236T	0237T
0238T	0243U	0247U	0278T	0285U	0288U	0295U	0296U	0303U
0304U	0305U	0310U	0316U	0319U	0320U	0323U	0329T	0331U
0338T	0339T	0345U	0346U	0347T	0347U	0348T	0348U	0349T
0349U	0350T	0350U	0351T	0352T	0353T	0353U	0354T	0356U
0358T	0361U	0372U	0376U	0377U	0384U	0385U	0386U	0387U
0389U	0390U	0394U	0395U	0398U	0401U	0402U	0403T	0404U
0406U	0407U	0412U	0415U	0416U	0418U	0422T	0437T	0439T
0440T	0442T	0443T	0444T	0445T	0469T	0481T	0505T	0506T
0523T	0525T	0526T	0527T	0528T	0529T	0530T	0531T	0532T
0541T	0542T	0543T	0545T	0547T	0553T	0553T	0554T	0555T
0557T	0558T	0559T	0560T	0561T	0562T	0567T	0568T	0569T
0570T	0583T	0596T	0597T	0598T	0599T	0602T	0603T	0613T
0619T	0620T	0627T	0628T	0629T	0630T	0632T	0635T	0636T
0637T	0638T	0639T	0643T	0644T	0645T	0646T	0648T	0649T
0652T	0653T	0654T	0664T	0665T	0666T	0667T	0668T	0669T
0670T	0686T	0689T	0690T	0691T	0693T	0694T	0695T	0696T
0697T	0698T	0707T	0708T	0709T	0710T	0711T	0712T	0713T
0714T	0716T	0717T	0718T	0719T	0721T	0723T	0725T	0726T
0727T	0728T	0729T	0730T	0731T	0732T	0733T	0734T	0736T
0737T	0738T	0739T	0740T	0741T	0743T	0744T	0745T	0746T
0747T	0748T	0749T	0750T	0764T	0765T	0766T	0767T	0770T
0771T	0772T	0773T	0774T	0776T	0777T	0778T	0779T	0781T

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Procedure Codes								
0782T	0791T	0792T	0793T	0794T	0795T	0796T	0797T	0798T
0799T	0800T	0801T	0802T	0803T	0804T	0805T	0806T	0807T
0808T	0810T	A4563	A4593	A4594	A6590	A6591	A9268	A9269
A9291	A9586	C1747	C1748	C1749	C1761	C1831	C7500	C9760
C9762	C9763	C9764	C9765	C9767	C9768	C9772	C9773	C9774
C9775	C9781	C9782	C9783	C9786	C9787	C9790	C9792	C9796
E1905	G0276	G9147	J1726	L8701	L8702	M0222	M0223	P2031
Q0221	Q0222	S2103	S2107	S2400	0421U	0422U	0429U	0435U
0814T	0815T	0823T	0824T	0825T	0826T	0857T	0861T	0862T
0863T	0865T	0866T	31242	31243	52284	90589	90623	90683
C1600	0439U	0440U	0441U	0443U	0446U	0447U	E0738	E0739
S9002								

IX. REFERENCES

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1. *Blue Cross and Blue Shield Association Medical Policy Program Policies and Procedures. Accessed June 2, 2022.*
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 Accessed June 1, 2022.*

X. POLICY HISTORY

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MP 4.002	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.
	1/6/2021 Administrative update. Revised code L8701 and L8702
	3/18/2021 Administrative update. Added CPT codes 0243U and 0247U. Deleted codes 0098U, 0099U, 0100U, K1010, K1011, K1012. Effective 4/1/2021
	07/01/2021 Administrative Update. The following new codes added to the policy 0251U, 0643T, 0644T, 0645T, 0646T, 0648T, 0649T, 0652T, 0653T,

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	0654T, 0664T, 0665T, 0666T, 0667T, 0668T, 0669T, 0670T, 90626, 90627, 90671, 90677, C1761 and G0237.
	8/31/2021 Administrative Update. Removed codes 90619, 90697, 0565T, and 0566T. Effective 10/1/2021.
	10/12/2021 Administrative Update. Removed code 0484T. Effective 11/1/2021.
	10/13/2021 Minor Review. Coding reviewed and updated. Policy statement unchanged. Updated references. Effective date 4/1/2022
	11/2/2021 Administrative Update. Removed code 0356T. Effective date 12/1/2021.
	11/17/2021 Administrative Update. Updated code G0237 to G0327 as this was an error. Effective date 12/1/2021.
	12/1/2021 Administrative Update. Removed codes 0139U, 0356T, 0423T, 0548T, 0549T, 0550T, 0551T, C9752, C9753. Added codes 0285U, 0288U 0295U, 0296U, 0303U, 0304U, 0305U, 0646T, 0686T, 0689T, 0690T, 0691T 0693T, 0694T, 0695T, 0696T, 0697T, 0698T, 0707T, 0708T, 0709T, 0710T, 0711T, 0712T, 0713T, 53451, 53452, 53453, 53454, 77089, 77090, 77091, 77092, 81560, 83529, 0297U, 0298U, 0299U, 0300U. Effective Date 1/1/2022
	1/5/2022 Administrative Update. Removed codes 0489T-0490T. Effective date 2/1/2022.
	03/11/2022 Administrative update. Removed deleted code 0151U. Added new codes 0308U, 0309U, 0310U, 0312U, 0316U, 0319U, 0320U, 0321U, A9291, C9781, C9782 and C9783. Effective 4/1/2022.
	4/7/2022 Administrative update. Removed CPT 81514. Effective 5/1/2022
	6/9/2022 Administrative update. Added CPT 0323U-0328U, 0331U, 0714T-0719T, 0721T-0734T, 0736T, 0737T, 90584. Effective 7/1/2022
	6/23/2022 Minor Review. Coding reviewed and updated. Policy statement unchanged. Effective 11/1/2022
	9/14/2022 Administrative update. Added CPT 0345U-0350U, 0353U, 0354U, C1834. Effective 10/1/2022
	12/2/2022 Administrative update. Added 30469, 87467, 90678, 0356U, 0361U, 0363U, 0738T-0750T, 0764T-0782T, C1747, C7500. Deleted 0475T-0478T, 0491T-0493T, 0499T, 0514T, Q0222, M0222, M0223. Effective 1/1/2023
	1/12/2023 Administrative update. Removed codes 0722T, 0724T, 0742T, and 0775T. Effective 4/1/2023. Removed Deleted codes 0324U, 0325U, C1834 & added new codes; 0369U-0374U, 0376U, 0377U, 0384U-0386U, A6590, A6591 & E1905 Effective 4/1/23.
	1/17/2023 Administrative update. Added 0004A, 0054A, 0064A, 0074A, 0083A, 0094A. Effective 3/1/2023
	4/3/2023 Administrative update. Added 0088U. Effective 5/1/2023
	5/8/2023 Administrative update. Added J1726. Effective 6/1/2023

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	6/5/2023 Administrative update. Removed 0715T. Added 0001A, 0002A, 0003A, 0011A, 0012A, 0013A, 0051A, 0052A, 0053A, 0071A, 0072A, 0073A, 0081A, 0082A, 0091A, 0092A, 0093A, 0111A, 0112A, 0113A, 91300, 91301, 91305, 91306, 91307, 91308, 91309, and 91311. Added 91303, 0031A, and 0034A. Effective 7/1/2023
	6/14/2023 Administrative update. Added 0387U, 0389U, 0390U, 0394U, 0395U, 0398U, 0399U, 0401U, 0791T, 0792T, 0793T, 0794T, 0795T, 0796T, 0797T, 0798T, 0799T, 0800T, 0801T, 0802T, 0803T, 0804T, 0805T, 0806T, 0807T, 0808T, 0810T, C9786, C9787. Effective 7/1/2023.
	7/6/2023 Administrative update. Removed 0363U. Added 90380,903851. Effective 8/1/2023.
	8/4/2023 Administrative update. Removed 0354U, 0328U. Added Q0221. Effective 9/1/2023
	9/7/2023 Administrative update. Removed 90678, 90380, 90381. Added 0061U, C9157, 0019M, 0402U, 0404U, 0406U, 0407U, 0412U, 0415U,0416U, 0418U, A9268, A9269, C9790, C9792. Effective 10/1/2023.
	10/5/2023 Administrative update. Removed 0308U, 0309U, 0369U, 0370U, 0371U, 0373U, 0374U, 0399U. Effective 11/1/2023.
	12/13/2023 Administrative update. Added 0421U, 0422U, 0429U, 0435U, 0814T, 0815T, 0823T, 0824T, 0825T, 0826T, 0857T, 0861T, 0862T, 0863T, 0865T, 0866T, 31242, 31243, 52284, 90589, 90623, 90683, C1600 Deleted 0508T, 0533T, 0534T, 0535T, 0536T, 0768T,0769T, C7561, C9157, C9788, K1009 91300, 0001A - 0004A, 91305, 0051A - 0054A, 91307, 0071A - 0074A, 91308, 0081A - 0083A, 91301, 0011A - 0013A, 91306, 0064A, 91308, 0091A - 0094A, 91311, 0111A - 0113A, 91303, 0031A, 0034A, 0041A, 0042A, 0044A. Effective 1/1/2024.
	3/15/2024 Administrative update. Deleted 0416U. Added 0439U, 0440U, 0441U, 0443U, 0446U, 0447U, A4593, A4594, C9796, E0738, E0739, S9002 effective 4/1/24

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