

MEDICAL POLICY

POLICY TITLE	EXPERIMENTAL AND INVESTIGATIONAL PROCEDURES
POLICY NUMBER	MP 4.002
CLINICAL BENEFIT	<input checked="" type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input checked="" type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input checked="" type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	11/1/2024

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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.

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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 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' 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

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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.

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	31242	31243	52284	53451	53452	53453	53454
87467	90584	90683	90637	90638	91132	91133	0015M	0019M
0020M	0025U	0061U	0063U	0066U	0067U	0077U	0088U	0095U
0105U	0106U	0107U	0108U	0110U	0114U	0115U	0116U	0117U
0119U	0121U	0122U	0123U	0174T	0175T	0220U	0221U	0234T
0235T	0236T	0237T	0238T	0243U	0247U	0278T	0285U	0288U
0295U	0303U	0304U	0305U	0310U	0329T	0331T	0331U	0332T
0338T	0339T	0345U	0346U	0347T	0348T	0349T	0350T	0350U
0351T	0352T	0353T	0354T	0356U	0358T	0361U	0372U	0376U
0377U	0384U	0385U	0386U	0387U	0389U	0390U	0394U	0395U
0398U	0401U	0403T	0404U	0406U	0407U	0412U	0415U	0416U
0418U	0421U	0422U	0422T	0429U	0435U	0437T	0439T	0439U
0440T	0440U	0441U	0442T	0443T	0443U	0444T	0445T	0446U
0447U	0450U	0451U	0452U	0456U	0457U	0458U	0462U	0463U
0464U	0466U	0469T	0472U	0481T	0505T	0506T	0508T	0525T
0526T	0527T	0528T	0529T	0530T	0531T	0532T	0541T	0542T
0543T	0545T	0547T	0553T	0554T	0555T	0557T	0558T	0559T

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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	0660T	0661T	0646T	0648T	0649T	0652T
0653T	0654T	0664T	0665T	0666T	0667T	0668T	0669T	0670T
0686T	0689T	0690T	0691T	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	0782T	0791T
0792T	0793T	0794T	0795T	0796T	0797T	0798T	0799T	0800T
0801T	0802T	0803T	0804T	0805T	0806T	0807T	0808T	0810T
0814T	0815T	0823T	0824T	0825T	0826T	0857T	0861T	0862T
0863T	0865T	0866T	0867T	0868T	0869T	0870T	0871T	0872T
0873T	0874T	0875T	0876T	0877T	0878T	0879T	0880T	0882T
0883T	0884T	0885T	0886T	0888T	0889T	0890T	0891T	0892T
0893T	0897T	0898T	0899T	0900T	A4593	A4594	A6590	A6591
A9268	A9269	A9291	A9586	C1600	C1605	C1747	C1748	C1749
C1761	C1831	C7500	C9760	C9762	C9763	C9764	C9765	C9766
C9767	C9768	C9772	C9773	C9774	C9775	C9781	C9782	C9783
C9786	C9792	C9796	E0738	E0739	E1905	G0276	G9147	J1726
J7355	L8701	L8702	M0222	M0223	P2031	Q0221	Q0222	S2103
S2107	S2400	S9002	J0172					

IX. REFERENCES

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1. *Blue Cross and Blue Shield Association Medical Policy Program Policies and Procedures. Accessed October 5, 2023.*

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- 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 October 5, 2003.

X. POLICY HISTORY

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MP 4.002	05/29/2020 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
	09/08/2020 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 0124U, 0125U, 0126U, 0127U, 0128U, 0405T and C9745. Effective 1/1/2021.
	01/06/2021 Administrative Update. Revised code L8701 and L8702
	03/18/2021 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, 0654T, 0664T, 0665T, 0666T, 0667T, 0668T, 0669T, 0670T, 90626, 90627, 90671, 90677, C1761 and G0237.
	08/31/2021 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
	11/02/2021 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.
12/01/2021 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	

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	01/05/2022 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.
	04/07/2022 Administrative Update. Removed CPT 81514. Effective 5/1/2022
	06/09/2022 Administrative Update. Added CPT 0323U-0328U, 0331U, 0714T-0719T, 0721T-0734T, 0736T, 0737T, 90584. Effective 7/1/2022
	06/23/2022 Minor Review. Coding reviewed and updated. Policy statement unchanged. Effective 11/1/2022
	09/14/2022 Administrative Update. Added CPT 0345U-0350U, 0353U, 0354U, C1834. Effective 10/1/2022
	12/02/2022 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
	01/12/2023 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.
	01/17/2023 Administrative Update. Added 0004A, 0054A, 0064A, 0074A, 0083A, 0094A. Effective 3/1/2023
	04/03/2023 Administrative Update. Added 0088U. Effective 5/1/2023
	05/08/2023 Administrative Update. Added J1726. Effective 6/1/2023
	06/05/2023 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
	06/14/2023 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.
	07/06/2023 Administrative Update. Removed 0363U. Added 90380,903851. Effective 8/1/2023.
	08/04/2023 Administrative Update. Removed 0354U, 0328U. Added Q0221. Effective 9/1/2023
	09/07/2023 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.
	10/05/2023 Administrative Update. Removed 0308U, 0309U, 0369U, 0370U, 0371U, 0373U, 0374U, 0399U. Effective 11/1/2023.

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	10/12/2023 Minor Review. Removed CPT Codes A4563, 0693T, 0523T, 0353U, 0349U, 0348U, 0347U, 0319U, 0316U, 0323U, 0320U, 0319U, 0316U, 0296U, 0202U, 0164U, 0112U, 0109U, 92519, 92518, 92517, 83529, 81560, 77092, 77091, 77090, 77089.
	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.
	03/15/2024 Administrative Update. Deleted 0416U. Added 0439U, 0440U, 0441U, 0443U, 0446U, 0447U, A4593, A4594, C9796, E0738, E0739, S9002 effective 4/1/24
	04/09/2024 Administrative Update. Added 0331T, 0332T effective 6/1/2024.
	06/05/2024 Administrative Update. Added 0660T, 0661T. Removed 90589, 90623. Effective 7/1/2024
	06/10/2024 Administrative Update. Deleted codes 03523U, C9787, C9790. Added codes 0020M, 0450U-0452U, 0456U-0458U, 0462U-0464U, 04666U, 0472U, 0867T-0880T, 0882T-0886T, 0888T-0893T, 0897T-0900T, 90637-8, C1605, J7355. Effective 7/1/2024.
	07/08/2024 Administrative Update. Removed code 0402U. Effective 8/1/2024.
	09/03/2024 Administrative Update. Added J0172. Effective 11/1/2024.

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