

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:	5/1/2025

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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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Experimental and investigational services (e.g., devices, drugs, procedures, supplies, technologies, treatments) are services whose safety or efficacy is not known, or are services that are used in a way that departs from generally accepted standards of practice in the medical community.

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 are based on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. 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. These medical policies 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

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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								
15011	15012	15013	15014	15015	15016	15017	15018	30468
30469	31242	31243	33267	33269	33370	52284	53451	53452
53453	53454	81558	83884	87467	90584	90624	90637	90638
91132	91133	0015M	0020M	0025U	0061U	0063U	0067U	0077U
0095U	0100T	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
0288U	0295U	0303U	0304U	0305U	0310U	0329T	0331T	0331U
0332T	0338T	0339T	0345T	0345U	0346U	0347T	0348T	0349T
0350T	0351T	0352T	0353T	0354T	0356U	0358T	0361U	0372U
0384U	0385U	0387U	0389U	0390U	0394U	0395U	0398U	0401U
0403T	0404U	0406U	0407U	0418U	0422T	0437T	0439T	0439U
0440U	0441U	0443T	0443U	0444T	0445T	0446U	0447U	0450U
0451U	0452U	0457U	0458U	0462U	0463U	0464U	0466U	0469T
0472T	0472U	0473T	0480U	0481T	0482U	0483U	0484U	0487U
0496U	0500U	0501U	0502U	0504U	0505T	0506T	0506U	0508U
0509U	0511U	0512U	0517U	0521U	0522U	0524U	0531T	0531U
0532T	0532U	0535U	0537U	0540U	0541T	0541U	0542T	0542U
0543T	0544T	0544U	0545T	0545U	0546U	0547T	0547U	0548U
0549U	0554T	0555T	0557T	0558T	0559T	0560T	0561T	0562T
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

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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	0804T	0805T
0806T	0807T	0808T	0810T	0814T	0815T	0826T	0857T	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	0901T	0902T	0903T	0904T	0905T	0932T
0935T	0936T	0937T	0938T	0939T	0940T	0946T	A4544	A4593
A4594	A6590	A6591	A7021	A9268	A9269	A9291	A9586	C1600
C1605	C1735	C1736	C1761	C1831	C7500	C8002	C9760	C9762
C9763	C9764	C9765	C9766	C9767	C9772	C9773	C9774	C9775
C9781	C9782	C9783	C9786	C9792	C9796	E0469	E0715	E0716
E0738	E0739	E0743	E0767	E1905	E3200	G0276	G0566	G9147
J1726	J7355	L8608	L8720	L8721	P2031	S2103	S2107	S2400
S9002								

IX. REFERENCES

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1. Blue Cross and Blue Shield Association Medical Policy Program Policies and Procedures.
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.

X. POLICY HISTORY

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MP 4.002	05/29/2020 Administrative Update. Added new codes effective 07/01/2020: 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

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	11/30/2020 Administrative Update. Added new codes 0623T, 0624T, 0625T, 0626T, 0633T, 0634T, 0635T, 0636T, 0637T, 0638T. Effective 01/01/2021.
	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 01/01/2021.
	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 04/01/2021
	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 10/01/2021.
	10/12/2021 Administrative Update. Removed code 0484T. Effective 11/01/2021.
	10/13/2021 Minor Review. Coding reviewed and updated. Policy statement unchanged. Updated references. Effective date 04/01/2022
	11/02/2021 Administrative Update. Removed code 0356T. Effective date 12/01/2021.
	11/17/2021 Administrative Update. Updated code G0237 to G0327 as this was an error. Effective date 12/01/2021.
	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 01/01/2022
	01/05/2022 Administrative Update. Removed codes 0489T-0490T. Effective date 02/01/2022.
	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 04/01/2022.
	04/07/2022 Administrative Update. Removed CPT 81514. Effective 05/01/2022
	06/09/2022 Administrative Update. Added CPT 0323U-0328U, 0331U, 0714T-0719T, 0721T-0734T, 0736T, 0737T, 90584. Effective 07/01/2022
	06/23/2022 Minor Review. Coding reviewed and updated. Policy statement unchanged. Effective 11/01/2022
	09/14/2022 Administrative Update. Added CPT 0345U-0350U, 0353U, 0354U, C1834. Effective 10/01/2022

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	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 01/01/2023
	01/12/2023 Administrative Update. Removed codes 0722T, 0724T, 0742T, and 0775T. Effective 04/01/2023. Removed Deleted codes 0324U, 0325U, C1834 & added new codes; 0369U-0374U, 0376U, 0377U, 0384U-0386U, A6590, A6591 & E1905 Effective 04/01/23.
	01/17/2023 Administrative Update. Added 0004A, 0054A, 0064A, 0074A, 0083A, 0094A. Effective 03/01/2023
	04/03/2023 Administrative Update. Added 0088U. Effective 05/01/2023
	05/08/2023 Administrative Update. Added J1726. Effective 06/01/2023
	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 07/01/2023
	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 07/01/2023.
	07/06/2023 Administrative Update. Removed 0363U. Added 90380,903851. Effective 08/01/2023.
	08/04/2023 Administrative Update. Removed 0354U, 0328U. Added Q0221. Effective 09/01/2023
	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 10/01/2023.
	10/05/2023 Administrative Update. Removed 0308U, 0309U, 0369U, 0370U, 0371U, 0373U, 0374U, 0399U. Effective 11/01/2023.
	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 01/01/2024.

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03/15/2024 Administrative Update. Deleted 0416U. Added 0439U, 0440U, 0441U, 0443U, 0446U, 0447U, A4593, A4594, C9796, E0738, E0739, S9002 effective 04/01/24
04/09/2024 Administrative Update. Added 0331T, 0332T effective 06/01/2024.
06/05/2024 Administrative Update. Added 0660T, 0661T. Removed 90589, 90623. Effective 07/01/2024
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 07/01/2024.
07/08/2024 Administrative Update. Removed code 0402U. Effective 08/01/2024.
09/18/2024 Administrative Update. New codes 0480U, 0482U, 0483U, 0484U, 0496U, 0500U, 0501U, 0502U, 0504U, 0506U, 0508U, 0509U, 0511U, 0512U, 0517U, 90624, E0715, E0716, E0767, E3200, L8720, L8721, A4544, E0743, 0487U, E0469, A7021 added effective 10/01/2024.
10/16/2024 Minor Review. Removed codes 0088U, 0350U, 0377U, 0412U, 0421U, 0422U, 0440T, 0442T, C1600, C1747, C1748, C1749, 90683, 0066U, 0386U, 0416U, 0508T, L8701, L8702.
12/11/2024 Administrative Update. Added 0521U 0522U, 0524U-0526U, 0528U, 0901T-0905T, 0932T, 0935T-0940T, 0946T 15011-15018, 81558, 82233, 83884, C1735, C1736, C8002, G0561, 0100T, 0472T, 0473T, L8608. Removed 0346U, 0456U, 0553T, 0567T, 0568T, 0616T, C9786, 90683. Effective 01/01/2025.
01/07/2025 Administrative Update. Removed G0561. Added 0484U effective 02/01/2025.
01/10/2025 Administrative Update. Added J9037 effective 03/01/2025.
01/22/2025 Administrative Update. Removed 0376U as this code is now in MP 2.280. Effective 05/01/2025.
03/12/2025 Administrative Update. Added codes 0531U, 0532U, 0537U, 0540U, 0541U, 0542U, 0544U, 0545U, 0546U, 0547U, G0566, 33267, 33269, 33370, 0544T, 0345T. Removed 0646T, 0795T-0803T, 0823T-0825T, 0861T-0863T, 0435U, 0019M, 0415U, 0429U, 0285U, J9037, M0222, M0223, Q0221, Q0222. Effective 04/01/2025.

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