

Experimental-Investigational Services

Policy # 00770

Original Effective Date: 03/01/2022

Current Effective Date: 01/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers charges for the services listed in this policy to be **investigational/experimental**.* Investigational is defined as a medical treatment, procedure, drug, device, or biological product where effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination the plan makes regarding a medical treatment, procedure, drug, device, or biological product is Investigational will consider the following:

- Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the Food and Drug Administration (FDA) and whether such approval has been granted when the medical treatment, procedure, drug, device, or biological product is sought to be furnished; **OR**
- Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, or improves health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - Consultation with the BCBSA evidence review policies or other non-affiliated technology evaluation centers.
 - Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; **OR**
 - Reference to regulations.

Policy Guidelines

Determinations are made by the Plan after BCBSLA's review of available scientific data. Evidence based physician specialty societal guidelines, opinions of experts in a particular field and opinions and assessments of nationally recognized review organizations may also be considered by the Plan but are not determinative or conclusive.

Experimental-Investigational Services

Policy # 00770

Original Effective Date: 03/01/2022

Current Effective Date: 01/01/2025

Medical and Scientific Evidence is defined by BCBSLA as one of the following:

- Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.
- Peer-reviewed literature or biomedical compendia from such sources as the National Institute of Health's National Library of Medicine or The Cochrane Library.
- An accepted indication for treatment in one of the following standard reference compendia:
 - The American Hospital Formulary Service-Drug Information,
 - The American Medical Association Drug Evaluations,
 - The American Dental Association Accepted Dental Therapeutics, and
 - The United States Pharmacopoeia Drug Information.
- Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the:
 - U.S. Department of Health and Human Services,
 - Federal Agency for Healthcare Research and Quality,
 - National Institutes of Health,
 - National Cancer Institute,
 - National Academy of Sciences,
 - Center for Medicare and Medicaid Services, and
 - Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, (non-affiliated technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Policy History

Original Effective Date: 03/01/2022

Current Effective Date: 01/01/2025

12/02/2021	Medical Policy Committee review
12/08/2021	Medical Policy Implementation Committee approval. New policy.
12/20/2021	Coding Update
03/17/2022	Coding Update
03/24/2022	Coding Update
03/28//2022	Coding Update
04/06/2022	Coding Update



Experimental-Investigational Services

Policy # 00770

Original Effective Date: 03/01/2022

Current Effective Date: 01/01/2025

04/13/2022	Coding Update
05/26/2022	Coding Update
06/20/2022	Coding Update
08/01/2022	Coding Update
08/17/2022	Coding Update
09/16/2022	Coding Update
10/03/2022	Coding Update
12/01/2022	Medical Policy Committee review
12/14/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/09/2023	Coding update
01/31/2023	Coding update
02/02/2023	Coding update
02/08/2023	Coding update
03/02/2023	Coding update
03/21/2023	Coding update
04/04/2023	Coding update
05/01/2023	Coding update
05/12/2023	Coding update
05/30/2023	Coding update
06/05/2023	Coding update
06/20/2023	Coding update
08/02/2023	Coding update
09/11/2023	Coding update
09/14/2023	Coding update
10/31/2023	Coding update
11/13/2023	Coding update
12/07/2023	Medical Policy Committee review
12/13/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2024	Coding update
03/27/2024	Coding update
04/17/2024	Coding update
06/14/2024	Coding update
06/27/2024	Coding update
07/25/2024	Coding update
09/23/2024	Coding update
10/10/2024	Coding update
12/05/2024	Medical Policy Committee review
12/11/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Deleted "An accepted indication for treatment of cancer in one of the



Experimental-Investigational Services

Policy # 00770

Original Effective Date: 03/01/2022

Current Effective Date: 01/01/2025

following standard reference compendia, for drugs approved by the FDA for treatment of cancer:

- o The National Comprehensive Cancer Network Drugs & Biologics Compendium
- o The Thomson Micromedex ®‡ DRUGDEX ®‡
- o The Elsevier Gold Standard's Clinical Pharmacology
- o Any other authoritative compendia as recognized periodically by the United States Secretary of Health and Human Services."

Also removed the word "Federal" from content.

01/16/2025 Coding update

03/26/2025 Coding update

04/09/2025 Coding update

Next Scheduled Review Date: 12/2025

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.



Experimental-Investigational Services

Policy # 00770

Original Effective Date: 03/01/2022

Current Effective Date: 01/01/2025

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0091U, 0095U, 0198U, 0282U, 0358U, 0398U, 0421U, 0470U, 0490U, 0491U, 0492U, 0495U, 0510U, 0512U, 0513U, 37790, 66683, 78434, 81506, 91132, 91133, 92520, 92572, 92972, 93998, 95060, 95065, 96904, 97037, 99605, 99606, 99607 Add code effective 04/01/2025: 0550U
DELETED CPT	Delete codes effective 12/11/2023: 0362U, 0405U, 0406U, 0410U, 81554 Delete codes effective 07/01/2024: 0108U, 0222U, 0268U, 0269U, 0270U, 0271U, 0272U, 0273U, 0274U, 0276U, 0277U, 0317U, 0331U, 0332U, 0333U, 0363U, 0389U, 0413U, 0414U, 0420U, 0422U, 0436U, 81493, 0017M Delete codes effective 02/01/2025: 0337U, 0338U, 0378U, 0464U
HCPCS	A4542, A4544, A4560, A4563, A4593, A4594, A4600, A7049, A9268, A9269, A9292, A9507, A9610, C1052, C1736, C1824, C1833, C1839, C9757, C9758, C9760, C9762, C9772, C9773, C9774, C9775, C9781, C9791, C9792, E0221, E0490, E0491, E0492, E0493, E0530, E0715, E0716, E0734, E0738, E0739, E0743, E0762, E0767, E1905, E3200, G0562, G0563, K1004, K1030, K1036, L2006, L5991, L8720, L8721, S9056 Add codes effective 04/01/2025: G0183, G0566
DELETED HCPCS	Delete codes effective 01/01/2024: C9788, K1002, K1018, K1019, Delete codes effective 07/01/2024: C9787, C9790 Delete codes effective 11/01/2024: A4543, A4596, E0721, E0732, S8930 Delete codes effective 01/01/2025: C9786, C9788, C9794, C9795
T-Codes	0100T, 0174T, 0175T, 0202T, 0207T, 0208T, 0209T, 0210T, 0211T, 0212T, 0213T, 0214T, 0215T, 0216T, 0217T, 0218T, 0219T, 0220T, 0221T, 0222T, 0234T, 0235T, 0236T, 0237T, 0238T, 0278T, 0308T, 0330T, 0331T, 0332T, 0333T, 0347T, 0348T, 0349T, 0350T, 0351T, 0352T, 0353T, 0354T, 0358T, 0378T, 0379T, 0408T, 0409T, 0410T, 0411T, 0412T, 0413T, 0414T, 0415T, 0416T, 0417T, 0418T, 0419T, 0420T, 0422T, 0439T, 0443T, 0444T, 0445T, 0464T, 0469T, 0472T, 0473T, 0481T, 0485T, 0486T, 0488T, 0494T, 0495T, 0496T, 0505T, 0506T, 0507T, 0512T, 0513T, 0552T, 0554T, 0555T, 0556T, 0557T, 0558T, 0563T, 0569T, 0570T, 0571T, 0572T, 0573T, 0574T, 0575T, 0576T, 0577T, 0578T, 0579T, 0580T, 0583T, 0591T, 0592T, 0593T, 0594T, 0596T, 0597T, 0598T, 0599T, 0600T, 0601T, 0602T, 0603T, 0607T, 0608T,



Experimental-Investigational Services

Policy # 00770

Original Effective Date: 03/01/2022

Current Effective Date: 01/01/2025

	0609T, 0610T, 0611T, 0612T, 0613T, 0615T, 0619T, 0620T, 0621T, 0622T, 0623T, 0624T, 0625T, 0626T, 0631T, 0632T, 0639T, 0640T, 0643T, 0644T, 0645T, 0646T, 0647T, 0652T, 0653T, 0654T, 0658T, 0659T, 0664T, 0665T, 0666T, 0667T, 0668T, 0669T, 0670T, 0672T, 0673T, 0674T, 0675T, 0676T, 0677T, 0678T, 0679T, 0680T, 0681T, 0682T, 0683T, 0684T, 0685T, 0686T, 0687T, 0688T, 0689T, 0690T, 0691T, 0692T, 0694T, 0695T, 0696T, 0697T, 0698T, 0700T, 0701T, 0704T, 0705T, 0706T, 0707T, 0710T, 0711T, 0712T, 0713T, 0714T, 0716T, 0719T, 0721T, 0722T, 0723T, 0724T, 0725T, 0726T, 0727T, 0728T, 0729T, 0730T, 0731T, 0732T, 0733T, 0734T, 0736T, 0737T, 0740T, 0741T, 0742T, 0743T, 0744T, 0745T, 0746T, 0747T, 0748T, 0749T, 0750T, 0764T, 0765T, 0770T, 0771T, 0772T, 0773T, 0774T, 0776T, 0777T, 0778T, 0779T, 0781T, 0782T, 0784T, 0785T, 0786T, 0787T, 0788T, 0789T, 0791T, 0793T, 0794T, 0805T, 0806T, 0807T, 0808T, 0814T, 0815T, 0820T, 0821T, 0822T, 0823T, 0824T, 0825T, 0826T, 0857T, 0858T, 0861T, 0862T, 0863T, 0864T, 0865T, 0866T, 0867T, 0868T, 0869T, 0870T, 0871T, 0872T, 0873T, 0874T, 0875T, 0876T, 0877T, 0878T, 0879T, 0880T, 0881T, 0882T, 0883T, 0884T, 0885T, 0886T, 0887T, 0888T, 0893T, 0894T, 0895T, 0896T, 0897T, 0898T, 0899T, 0900T, 0901T, 0902T, 0903T, 0904T, 0905T, 0906T, 0907T, 0908T, 0909T, 0910T, 0911T, 0912T, 0915T, 0916T, 0917T, 0918T, 0919T, 0920T, 0921T, 0922T, 0923T, 0924T, 0925T, 0926T, 0927T, 0928T, 0929T, 0930T, 0931T, 0932T, 0933T, 0934T, 0935T, 0936T, 0937T, 0938T, 0939T, 0940T, 0941T, 0942T, 0943T, 0944T, 0946T, 0947T
DELETED T- CODES	Delete codes effective 01/01/2024: 0424T, 0425T, 0426T, 0427T, 0428T, 0429T, 0430T, 0431T, 0432T, 0433T, 0434T, 0435T, 0436T, 0508T, 0641T, 0642T, 0715T Delete codes effective 09/01/2024: 0483T, 0484T Delete codes effective 10/01/2024: 0660T, 0661T Delete codes effective 11/01/2024: 0783T Delete codes effective 01/01/2025: 0567T, 0568T, 0616T, 0617T, 0618T Delete codes effective 04/18/2025: 0633T, 0634T, 0635T, 0636T, 0637T, 0638T



Experimental-Investigational Services

Policy # 00770

Original Effective Date: 03/01/2022

Current Effective Date: 01/01/2025

***Investigational** – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

