Experimental-Investigational Services

Policy #   00770
Original Effective Date: 03/01/2022
Current Effective Date: 01/01/2024

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, 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 BCBSLA makes that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the United States 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**
- 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:
    - consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other non-affiliated technology evaluation center(s)
    - credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; **OR**
    - reference to federal regulations.

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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.

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.
- An accepted indication for treatment of cancer in one of the following standard reference compendia, for drugs approved by the FDA for treatment of cancer:
  - The National Comprehensive Cancer Network Drugs & Biologics Compendium
  - The Thomson Micromedex ®‡ DRUGDEX ®‡
  - The Elsevier Gold Standard's Clinical Pharmacology
  - Any other authoritative compendia as recognized periodically by the United States Secretary of Health and Human Services.
- 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

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       o   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, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Policy History

Original Effective Date: 03/01/2022
Current Effective Date: 01/01/2024
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
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

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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

Next Scheduled Review Date: 12/2024

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 2022 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,

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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.

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, 0222U, 0268U, 0269U, 0270U, 0271U, 0272U, 0273U, 0274U, 0276U, 0277U, 0282U, 0317U, 0331U, 0332U, 0333U, 0337U, 0338U, 0358U, 0363U, 0378U, 37790, 78434, 81506, 91132, 91133, 92520, 92572, 93998, 95060, 95065, 96904, 99605, 99606, 99607, 0017M Add code effective 07/01/2023: 81493, 0389U, 0398U Add codes effective 10/01/2023: 0413U, 0414U Add code effective 12/01/2023: 0108U Add codes effective 01/01/2024: 0420U, 0421U, 0422U, 0436U, 92972, 97037 Delete code effective 07/01/2022: 57465, 80187, 80235, 80285, 82107, 82610, 82777, 83631, 83876, 83951, 84449, 86486, 92145, 92576, 0007U, 0010U Delete codes effective 10/01/2022: 70557, 70558, 70559 Delete code effective 03/01/2023: 70371 Delete code effective 06/01/2023: 0341U Delete code effective 07/01/2023: 0315U Delete code effective 10/01/2023: 0386U Delete codes effective 12/11/2023: 0362U, 0380U, 0405U, 0406U, 0410U, 81554

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HCPCS	A4560, A4563, A4596, A4600, A9507, C1052, C1824, C1833, C1839, C9757, C9758, C9760, C9772, C9773, C9774, C9775, C9781, E0221, E0762, E1905, K1004, K1030, L2006, S8930, S9056 Add codes effective 07/01/2023: C9786, C9787 Add codes effective 09/01/2023: K1018, K1019 Add codes effective 10/01/2023: A9268, A9269, A9292, C9788, C9790, C9791, C9792, K1036, L5991 Add codes effective 01/01/2024: A4542, A7049, C9794, C9795, E0490, E0491, E0492, E0493, E0530, E0732, E0734 Delete codes effective 07/01/2022: A4639, A7047, A9589, A9597, A9598, B4105, J0591, J3570, Q3014, S8092 Delete codes effective 08/01/2022: G2170, G2171 Delete code effective 09/01/2022: C8937 Delete code effective 03/01/2023: C2623 Delete codes effective 01/01/2024: C9788, K1002, K1018, K1019
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, 0483T, 0484T, 0485T, 0486T, 0488T, 0494T, 0495T, 0496T, 0505T, 0506T, 0507T, 0512T, 0513T, 0552T, 0554T, 0555T, 0556T, 0557T, 0558T, 0563T, 0567T, 0568T, 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, 0609T, 0610T, 0611T, 0612T, 0613T, 0615T, 0616T, 0617T, 0618T, 0619T, 0620T, 0621T, 0622T, 0623T, 0624T, 0625T, 0626T, 0631T, 0632T, 0633T, 0634T, 0635T, 0636T, 0637T, 0638T, 0639T, 0640T, 0643T, 0644T, 0645T, 0646T, 0647T, 0652T, 0653T, 0654T, 0658T, 0659T, 0660T, 0661T, 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,

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	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, 0783T Add codes effective 07/01/2023: 0791T, 0793T, 0794T, 0805T, 0806T, 0807T, 0808T Add code effective 09/01/2023: 0692T Add code effective 01/01/2024: 0784T, 0785T, 0786T, 0787T, 0788T, 0789T, 0814T, 0815T, 0820T, 0821T, 0822T, 0857T, 0858T, 0861T, 0862T, 0863T, 0864T, 0865T, 0866T Delete codes effective 07/01/2022: 0479T, 0480T Delete codes effective 10/01/2022: 0054T, 0055T Delete codes effective 11/01/2022: 0717T, 0718T Delete codes effective 01/01/2023: 0470T, 0471T, 0487T, 0491T, 0492T, 0493T, 0702T, 0703T Delete code effective 02/01/2023: 0184T Delete code effective 05/01/2023: 0629T, 0630T Delete code effective 07/01/2023: 0465T Delete code effective 09/01/2023: 0440T Delete code effective 10/01/2023: 0437T Delete codes effective 01/01/2024: 0424T, 0425T, 0426T, 0427T, 0428T, 0429T, 0430T, 0431T, 0432T, 0433T, 0434T, 0435T, 0436T, 0508T, 0641T, 0642T, 0715T

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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.