BSC9.01	Investigational Services		
Original Policy Date:	June 1, 2025	**Effective Date:**	January 1, 2026
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Policy Statement

This Medical Policy addresses Healthcare Services that are not covered because they are considered investigational.

I. Healthcare Services which do not meet ALL of the following five (5) elements are considered **investigational**:
   A. The technology must have final approval from the appropriate government regulatory bodies.
   B. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
   C. The technology must improve the net health outcome.
   D. The technology must be as beneficial as any established alternatives.
   E. The improvement must be attainable outside the investigational setting.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Investigational Assessment

The descriptions in this Policy Guidelines section provide additional information regarding the five (5) elements identified in the Policy Statement:

A. The technology must have final approval from the appropriate government regulatory bodies.
   - This criterion applies to drugs, biological products, devices and any other product or procedure that must have final approval to market from the U.S. Food and Drug Administration ("FDA") or any other federal governmental body with authority to regulate the use of the technology.
   - Any approval that is granted as an interim step in the FDA's or any other federal governmental body's regulatory process is not sufficient.
   - The indications for which the technology is approved need not be the same as those which Blue Shield of California is evaluating.

B. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
   - The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence.
   - The evidence should demonstrate that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence, or a convincing argument based on established medical facts that such measurement or alteration affects health outcomes.

C. The technology must improve the net health outcome.
   - The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.

D. The technology must be as beneficial as any established alternatives.
   - The technology should improve the net health outcome as much as, or more than, established alternatives.

E. The improvement must be attainable outside the investigational setting.
   - When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy Criteria C and D.

The list of Healthcare Services and their associated codes in this Medical Policy is intended as a general reference and may not cover all Healthcare Services. The enumeration of Healthcare Services considered investigational within this Medical Policy is not exhaustive and does not include all Healthcare Services classified as investigational under separate Blue Shield of California medical policies.

Coding
See the Codes table for details.

Description

As described above in the Policy Statement, this Medical Policy addresses Healthcare Services that are not covered because they are considered investigational. It generally includes Healthcare Services that do not require clinical review to determine if they are Medically Necessary because the safety and/or effectiveness have not been demonstrated through a comprehensive review of established published medical and scientific literature or due to insufficient evidence supporting their efficacy and safety.

Related Policies

- Laboratory Testing Investigational Services

Benefit Application

Benefit determinations should be based in all cases on the applicable member health services contract language. To the extent there are conflicts between this Medical Policy and the member health services contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal law may prohibit health plans from denying FDA-approved Healthcare Services as investigational or experimental. In these instances, Blue Shield of California may be obligated to determine if these FDA-approved Healthcare Services are Medically Necessary.

Regulatory Status

- N/A

Rationale

- N/A

References

1. American Medical Association. (2025). CPT. Retrieved on December 15, 2025 from https://www.ama-assn.org/practice-management/cpt
2. Blue Shield of California, Medical Policy Committee, Policy and Procedures: Technology Assessment.
3. Centers for Medicare & Medicaid Services. (2025). Healthcare Common Procedure Coding System (HCPCS). Retrieved on December 15, 2025 from https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system

Documentation for Clinical Review

- No records required

Coding

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.

Type	Code	Description
CPT®	36837	Percutaneous arteriovenous fistula creation, upper extremity, separate access sites of the peripheral artery and peripheral vein, including fistula maturation procedures (e.g., transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation
	64628	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral
	64629	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure)
	84112	Evaluation of cervicovaginal fluid for specific amniotic fluid protein(s) (e.g., placental alpha microglobulin-1 [PAMG-1], placental protein 12 [PP12], alpha-fetoprotein), qualitative, each specimen
	0219T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical
	0312U	Autoimmune diseases (e.g., systemic lupus erythematosus [SLE]), analysis of 8 IgG autoantibodies and 2 cell-bound complement activation products using enzyme-linked immunosorbent immunoassay (ELISA), flow cytometry and indirect immunofluorescence, serum, or plasma and whole blood, individual components reported along with an algorithmic SLE-likelihood assessment
	0394T	High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed
	0395T	High dose rate electronic brachytherapy, interstitial or intracavitary treatment, per fraction, includes basic dosimetry, when performed

Type	Code	Description
	0623T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission, computerized analysis of data, with review of computerized analysis output to reconcile discordant data, interpretation and report
	0646T	Transcatheter tricuspid valve implantation (TTVI)/replacement with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed
	0649T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure); single organ (List separately in addition to code for primary procedure)
	0673T	Ablation, benign thyroid nodule(s), percutaneous, laser, including imaging guidance
	0686T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance
	0735T	Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with primary craniotomy (List separately in addition to code for primary procedure)
	0753T	Digitization of glass microscope slides for level IV, surgical pathology, gross and microscopic examination (List separately in addition to code for primary procedure)
	0988T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (e.g., array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous and subfascial ***(Code effective 1/1/2026)***
	0989T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subcutaneous and subfascial ***Code effective 1/1/2026)***
	0990T	Transcervical instillation of biodegradable hydrogel materials, intrauterine ***(Code effective 1/1/2026)***
	0991T	Cystourethroscopy, with low-energy lithotripsy and acoustically actuated microspheres, including imaging ***(Code effective 1/1/2026)***
	0992T	Noninvasive assessment of cardiac risk derived from augmentative software analysis of perivascular fat without concurrent computed tomography (CT) scan of the heart, including patient-specific clinical factors, with interpretation and report by a physician or other qualified health care professional ***(Code effective 1/1/2026)***
	0993T	Noninvasive assessment of cardiac risk derived from augmentative software analysis of perivascular fat with concurrent computed tomography scan of the heart, including patient-specific clinical factors, with interpretation and report by a physician or other qualified health care professional (List separately in addition to code for primary procedure) ***(Code effective 1/1/2026)***

Type	Code	Description
	0994T	Endovascular delivery of aortic wall stabilization drug therapy through a sheath positioned within an abdominal aortic aneurysm, with aortic roadmapping, balloon occlusion, imaging guidance, and radiological supervision and interpretation; percutaneous ***(Code effective 1/1/2026)***
	0995T	Endovascular delivery of aortic wall stabilization drug therapy through a sheath positioned within an abdominal aortic aneurysm, with aortic roadmapping, balloon occlusion, imaging guidance, and radiological supervision and interpretation; open ***(Code effective 1/1/2026)***
	0996T	Insertion and scleral fixation of a capsular bag prosthesis containing an intraocular lens prosthesis, with vitrectomy, including removal of crystalline lens or dislocated intraocular lens prosthesis, when performed ***(Code effective 1/1/2026)***
	0997T	Precutaneus magnetic stimulation; treatment planning using magnetic resonance imaging-guided neuronavigation to determine optimal location, dose, and intensity for magnetic stimulation therapy, derived from evoked potentials from single pulses of electromagnetic energy recorded by 64-channel electroencephalogram, including automated data processing, transmission, analysis, generation of treatment parameters with review, interpretation, and report ***(Code effective 1/1/2026)***
	0998T	Precutaneus magnetic stimulation; personalized treatment delivery of magnetic stimulation therapy to a prespecified target area derived from analysis of evoked potentials within the precuneus, utilizing magnetic resonance imaging-based neuronavigation, with management, per day ***(Code effective 1/1/2026)***
	0999T	Autologous muscle cell therapy, harvesting of muscle progenitor cells, including ultrasound guidance, when performed ***(Code effective 1/1/2026)***
	1000T	Autologous muscle cell therapy, administration of muscle progenitor cells into the urethral sphincter, including cystoscopy and post-void residual ultrasound, when performed ***(Code effective 1/1/2026)***
	1001T	Autologous muscle cell therapy, injection of muscle progenitor cells into the external anal sphincter, including ultrasound guidance, when performed ***(Code effective 1/1/2026)***
	1002T	Air displacement plethysmography, whole-body composition assessment, with interpretation and report ***(Code effective 1/1/2026)***
	1003T	Arthroplasty, first carpometacarpal joint, with distal trapezial and proximal first metacarpal prosthetic replacement (e.g., first carpometacarpal total joint) ***(Code effective 1/1/2026)***
	1004T	Electronic analysis of implanted sub-scalp continuous bilateral electroencephalography monitoring system (e.g., contact group[s], gain, bandpass filters) by physician or other qualified health care professional; without programming ***(Code effective 1/1/2026)***
	1005T	Electronic analysis of implanted sub-scalp continuous bilateral electroencephalography monitoring system (e.g., contact group[s], gain, bandpass filters) by physician or other qualified health care professional; with programming, first 15 minutes face-to-face time with physician or other qualified health care professional ***(Code effective 1/1/2026)***
	1006T	Electronic analysis of implanted sub-scalp continuous bilateral electroencephalography monitoring system (e.g., contact group[s], gain, bandpass filters) by physician or other qualified health care professional; with programming, each additional 15 minutes face-to-face time with

Type	Code	Description
		physician or other qualified health care professional (List separately in addition to code for primary procedure) ***(Code effective 1/1/2026)***
	1007T	Electroencephalogram from implanted sub-scalp continuous bilateral electroencephalography monitoring system, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and report, up to 30 days of recording, without video ***(Code effective 1/1/2026)***
	1008T	Remote monitoring of sub-scalp implanted continuous bilateral electroencephalography monitoring system, device fitting, initial set-up, and patient education in wearing of system and use of equipment ***(Code effective 1/1/2026)***
	1009T	Remote monitoring of a sub-scalp implanted continuous bilateral electroencephalography monitoring system, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and report, up to 30 days of recording without video ***(Code effective 1/1/2026)***
	1010T	Computerized ophthalmic analysis of monocular eye movements using retinal-based eye-tracking without spatial calibration, including fixation, microsaccades, drift, and horizontal saccades, when performed, unilateral or bilateral, with interpretation and report ***(Code effective 1/1/2026)***
	1011T	Photobiomodulation (PBM) therapy of oral cavity, including placement of an oral device, monitoring of patient tolerance to treatment, and removal of the oral device ***(Code effective 1/1/2026)***
	1012T	Motorized ab interno trephination of sclera (sclerostomy), or trabecular meshwork (trabeculostomy), 1 or more, including injection of antifibrotic agents, when performed ***(Code effective 1/1/2026)***
	1013T	Laparoscopy, surgical, implantation or replacement of lower esophageal sphincter neurostimulator electrode array and neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver, including cruroplasty and/or electronic analysis, when performed ***(Code effective 1/1/2026)***
	1014T	Laparoscopic revision or removal, lower esophageal sphincter neurostimulator electrodes ***(Code effective 1/1/2026)***
	1015T	Revision or removal, lower esophageal sphincter neurostimulator pulse generator or receiver ***(Code effective 1/1/2026)***
	1016T	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements), lower esophageal sphincter neurostimulator pulse generator/transmitter; intraoperative, with programming ***(Code effective 1/1/2026)***
	1017T	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements), lower esophageal sphincter neurostimulator pulse generator/transmitter; subsequent, without reprogramming ***(Code effective 1/1/2026)***
	1018T	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements), lower esophageal sphincter

Type	Code	Description
		neurostimulator pulse generator/transmitter; subsequent, with reprogramming ***(Code effective 1/1/2026)***
	1019T	Lymphovenous bypass, including robotic assistance, when performed, per extremity ***(Code effective 1/1/2026)***
	1020T	Raman spectroscopy of 1 or more skin lesions, with probability score for malignant risk derived by algorithmic analysis of data from each lesion ***(Code effective 1/1/2026)***
	1021T	Active thoracic irrigation (separate procedure) ***(Code effective 1/1/2026)***
	1022T	Percutaneous tissue displacement, any method, including imaging guidance; intra-abdominal/pelvic structures (List separately in addition to code for primary procedure) ***(Code effective 1/1/2026)***
	1023T	Percutaneous tissue displacement, any method, including imaging guidance; intrathoracic structures (List separately in addition to code for primary procedure) ***(Code effective 1/1/2026)***
	1024T	Percutaneous tissue displacement, any method, including imaging guidance; soft tissue (List separately in addition to code for primary procedure) ***(Code effective 1/1/2026)***
	1025T	Alternating electric fields dosimetry and delivery-simulation modeling, creation and selection of patient-specific array layouts, and placement verification ***(Code effective 1/1/2026)***
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
06/01/2025	New policy.
01/01/2026	Administrative update. Coding update. Policy title changed from Investigational or Experimental Services to current one.

Feedback

Blue Shield of California is interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration. Our medical policies are available to view or download at www.blueshieldca.com/provider.

For medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health

services contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE Red font: Verbiage removed	**AFTER**
Investigational or Experimental Services BSC9.01 **Policy Statement:** This Medical Policy addresses Healthcare Services that are not covered because they are considered investigational or experimental. I. Healthcare Services which do not meet ALL of the following five (5) elements are considered **investigational or experimental**: A. The technology must have final approval from the appropriate government regulatory bodies. B. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes. C. The technology must improve the net health outcome. D. The technology must be as beneficial as any established alternatives. E. The improvement must be attainable outside the investigational setting.	**Investigational Services BSC9.01** **Policy Statement:** This Medical Policy addresses Healthcare Services that are not covered because they are considered investigational. I. Healthcare Services which do not meet ALL of the following five (5) elements are considered **investigational**: A. The technology must have final approval from the appropriate government regulatory bodies. B. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes. C. The technology must improve the net health outcome. D. The technology must be as beneficial as any established alternatives. E. The improvement must be attainable outside the investigational setting.