New and Emerging Technology - Coverage Status

LOB(s): ☒ *Commercial* ☒ *Medicare*	*State(s):* ☒ *Idaho* ☒ *Montana* ☒ *Oregon* ☒ *Washington* ☐ *Other:*
☒ *Medicaid*	☒ *Oregon*

Enterprise Policy

PacificSource is committed to assessing and applying current regulatory standards, widely-used treatment guidelines, and evidenced-based clinical literature when developing clinical criteria for coverage determination. Each policy contains a list of sources (references) that serves as the summary of evidence used in the development and adoption of the criteria. The evidence was considered to ensure the criteria provide clinical benefits that promote patient safety and/or access to appropriate care. Each clinical policy is reviewed, updated as needed, and readopted, at least annually, to reflect changes in regulation, new evidence, and advancements in healthcare.

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determinations are Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

Background

New and emerging medical and behavioral healthcare procedures, pharmaceuticals, and devices (collectively "technologies") are often prescribed by physicians and/or marketed to the public before FDA or other government agency approval, or research is available in peer-reviewed literature documenting efficacy, safety, and long-term positive outcomes.

New and emerging technologies are reviewed by the New Technologies and Operational Criteria (NTOC) Committee which is chaired by a PacificSource Medical Director. The PacificSource Behavioral Health Medical Director or behavioral healthcare professional designee is involved in the decision-making process for behavioral healthcare services. Pharmaceuticals are reviewed by the PacificSource Pharmacy and Therapeutics (P&T) Committee.

The NTOC Committee bases its recommendation of coverage on review and evaluation of the following resources:

- Available peer-reviewed and evidenced-based literature
- Survey of standards of care and coverage
- Consultation with specialists and expert professionals
- PacificSource group and individual contracts

- Medicare and Medicaid requirements

This “New and Emerging Technologies – Coverage Status” policy outlines the evaluation process of new and emerging technology as well as coverage status of items considered experimental, investigational, or unproven.

Procedure

Commercial

Evaluation Process

The NTOC Committee reviews and evaluates new technology and new application of existing technology of medical and behavioral healthcare procedures and devices. NTOC Committee members represent key departments and stakeholders who have operational insight or responsibility for applying the criteria developed by the Committee. A PacificSource Medical Director chairs the NTOC Committee and ensures the Behavioral Health Medical Director or behavioral healthcare professional designee is involved in the decision-making process for behavioral healthcare services.

Agenda items for the NTOC Committee to review for coverage status are collected from multiple sources, which include, but are not limited to:

- New CPT or HCPCS codes
- New FDA approvals
- Provider inquiries
- Reports of new technology acquired by a community provider or anticipated to have widespread acceptance
- Utilization reviews or trends
- Vendor requests – vendor requests for reassessment of coverage position are limited to an annual review unless there is a change in FDA status or Hayes, Inc. rating

To inform its decision-making, the NTOC Committee reviews peer-reviewed and evidence-based information, which indicates if the technology is in general use or a community standard, is under continued scientific review (testing/research), is shown to have a demonstratable benefit, or is shown to be safe and efficacious. The reviews may consist of the following:

- Technology assessment consisting of:
    - Information from appropriate government regulatory bodies such as Food and Drug Administration (FDA) and Centers for Medicare & Medicaid Services (CMS)
        - FDA approval alone is not a basis for coverage
    - Assessment of peer-reviewed literature and their conclusions concerning:
        - Effect of the technology on health outcomes, with emphasis on random controlled clinical trial outcomes
        - Evidence comparing new technology to established alternatives
        - Results attained outside of investigational settings, with emphasis on studies that were not underwritten by the manufacturer or other sponsor with financial interest in the service or technology

    - Reports on long-term studies indicating improved health outcomes and/or clinical trials in process or recruiting

- Information available from evidence-based resources may vary depending on treatment procedure or device (additional resources may be reviewed as necessary based on the technology being reviewed). The evidenced-based resources, which rely on the judgment of experts, include but are not limited to the resources found in the *Clinical Resources Used for Medical Necessity Determinations When No Other UM Clinical Criteria or Guideline Exists policy*
- Survey of similar market carriers and their published coverage position and/or medical policy concerning the service of technology under review
- PacificSource utilization and authorization data, as available and applicable

The PacificSource Medical Director may seek input or consult with specialists and professionals who have expertise in a specific technology when additional information is needed.

The NTOC committee, which includes a Medical Director, makes a determination based on the review of the technology that results in either:

- A covered service, which may include developing specific clinical guidelines criteria
- Experimental, Investigational, or Unproven (E/I/U) determination, which is added to the "New and Emerging Technologies – Coverage Status" policy or as an E/I/U item to an existing policy related to the technology reviewed
    - A technology may remain unproven and will not be reviewed annually (unless there is a request or increased utilization) when the following conditions are met:
        - The scientific evidence does not support clinical efficacy of the technology demonstrated by **ONE** of the following:
            - There is no general use within the medical community, i.e., the technology does not meet community standards
            - There have not been clinical studies for five or more years, indicating the technology is no longer under scientific review
            - The technology has not been proven to have a demonstrate able benefit or been shown to be safe and efficacious
    - The unproven technology which is not reviewed annually, will be tracked and noted, along with associated codes, as not annually reviewed in NTOC documentation.

Quality Oversight

The "New and Emerging Technologies – Coverage Status" policy will be reviewed at least annually.

In addition, UM staff designated by the Director of UM will present an annual report summarizing the NTOC review activity is presented to our Clinical Quality and Utilization Management (CQUM) committee, which consists of external providers and PacificSource Medical Directors, for review.

Medicaid

PacificSource Community Solutions (PCS) follows Excluded Services Guidelines E1 and E2 of the Oregon Health Plan (OHP) Prioritized List of Health Services for guidance on New and Emerging Technology.

In the absence of coverage guidance on the OHP Prioritized List, Oregon Administrative Rules (OARs), CMS guidelines and criteria, PCS will follow commercial criteria within a specific PacificSource policy, as applicable, or external criteria for determination of coverage and medical necessity coverage.

Medicare

PacificSource Medicare follows CMS guidelines and criteria. In the absence of CMS guidelines and criteria, PacificSource Medicare will follow commercial criteria within a specific PacificSource policy, as applicable, or external criteria for determination of coverage and medical necessity coverage.

Experimental/Investigational/Unproven Determinations for Coverage Status

The new and emerging medical technologies in the following list have been determined by the NTOC Committee to be experimental, investigational, or unproven (E/I/U) and therefore are not considered medically necessary or covered. The impact of these technologies on health outcomes has not been established as the current scientific evidence is either not yet sufficient or does not support clinical efficacy.

The NTOC Committee has the authority to add new technologies or revise the determinations listed below based on additional review of current scientific evidence, advice, and recommendations by the NTOC Committee.

Experimental/Investigational/Unproven Determinations for Coverage Status

The following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

PROCEDURE	CPT HCPCS	COVERAGE STATUS
AcuDetox (Auricular Acupuncture) treatment Addiction/substance abuse disorder or any other indication.	No Specific Code 97810, 97811	Not Covered (Experimental/Investigational/Unproven) (Review Contract for coverage)
Baroreflex Activation Therapy (BAT) Modulation System (Barostim NEO System) reducing blood pressure or resistant hypertension	64654, 64655, 64656, 64657, 64658, 64659, 93145, 93146	Not Covered (Experimental/Investigational/Unproven)
Bone Marrow Aspirate Concentrate (BMAC) therapy & Hematopoietic progenitor cell (HPC) used alone or in combination with other bone graft materials for all orthopedic applications including adjunct to spinal surgery	38230, 38241, 38232	Not Covered (Experimental/Investigational/Unproven) Exception: Bone Marrow Aspiration for transplant members
Botox injections for Cricopharyngeal (CP) dysfunction	No Specific Code 31571, 43499, 43236	Not Covered (Experimental/Investigational/Unproven)

PROCEDURE	CPT HCPCS	COVERAGE STATUS
Ceramics/Calcium Bone Void Fillers (also known as synthetic bone void fillers); (e.g., PRO-DENSE Regenerative Graft) used alone or in combination with other bone graft materials or bone marrow aspirate for all indications	No Specific Code 20900, 20902	Not Covered (Experimental/Investigational/Unproven)
Clinicom software platform for all indications	No Specific Code 96127, 96130, 96136, 96138	Not Covered (Experimental/Investigational/Unproven)
Coil embolization of hemorrhoids (HAE) (Emborrhoid technique) embolization of the hemorrhoidal arteries.	No Specific Code 37244	Not Covered (Experimental/Investigational/Unproven)
Cryoablation for chronic rhinitis (allergic or nonallergic) (e.g., ClariFix device)	No Specific Code 31243	Not Covered (Experimental/Investigational/Unproven)
Deep Brain Stimulation (e.g., Reclaim DBS) for Obsessive-compulsive disorder and comorbid psychiatric disorders.	No specific Code **CPT Codes:** 61863, 61864, 61867, 61868, 61880, 61850, 61860; 61885, 61886, 61888 **HCPC Codes:** L8680, L8685, L8686, L8687, L8688	Not Covered (Experimental/Investigational/Unproven)
EarliPoint™ Evaluation - for diagnosing and assessing autism in children 16 to 30 months old	No specific Code 96110, 96146	Not Covered (Experimental/Investigational/Unproven)
Erector Spinae Pain block (ESP block) (paraspinal fascial plane block) for all indications	No Specific Code 64999	Not Covered (Experimental/Investigational/Unproven)
External Trigeminal Nerve Stimulation (eTNS) System (e.g., Monarch) indication ADHD in children aged 7 to 12 years	E0733, A4541	Not Covered (Experimental/Investigational/Unproven)
External upper limb tremor stimulator (TAPS Therapy (Transcutaneous Afferent Patterned Stimulation) (e.g., Cala	E0734, A4542	Not Covered (Experimental/Investigational/Unproven)

PROCEDURE	CPT HCPCS	COVERAGE STATUS
One; Cala Trio) for essential tremors or Parkinson's Disease		
Gait Analysis (comprehensive, computer-based motion analysis technique) for all indications.	No Specific Code 96000, 96001, 96004	Not Covered (Experimental/Investigational/Unproven)
Ganglion Impar block for Coccydynia, pelvic pain, and all other indications	No Specific Code 64999	Not Covered (Experimental/Investigational/Unproven)
Ingestible "Vibrant Capsule Devices," also known as an Ingestible vibrating capsules or Vibrant Gastro System for chronic idiopathic constipation and all other indications	A9268, A9269	Not Covered (Experimental/investigational/Unproven)
Intense Pulse Light Therapy for the treatment of dry eyes from meibomian gland dysfunction	No Specific Code 17999	Not Covered (Experimental/investigational/Unproven)
Interactive Metronome Training (e.g., attention deficit hyperactivity disorder or any other indication)	No Specific Code 97039, 97139, 97799 **Therapy codes:** 97110, 97112	Not Covered (Experimental/Investigational/Unproven)
Intravascular Lithotripsy (IVL) – (Shockwave intravascular lithotripsy system (IVL) Coronary) for all indications	92972, 37262, 37279, C7571	Not Covered (Experimental/Investigational/Unproven)
Jaw Motion Rehab System (e.g., TheraBite Jaw Motion Rehabilitation System, OraStretch press, and Dynasplint Trismus System) – all indications	No Specific Code E1700, E1701, E1702	Not Covered (Experimental/Investigational/Unproven)
LimFlow System for Transcatheter Arterialization of Deep Veins (TADV) for all indications	C1889	Not Covered (Experimental/Investigational/Unproven)
LipiView II and LipiScan Ocular Surface Interferometer images Technique (diagnose and monitor meibomian gland dysfunction (MGD) and dry eye syndrome)	92285, 0330T, 0507T	Not Covered (Experimental/Investigational/Unproven)
Magnetic Resonance Neurography (MRN), (also known as Magnetic Resonance Neurogram or MR Imaging of the Peripheral Nerves	No Specific Code 76498	Not Covered (Experimental/Investigation/Unproven)

PROCEDURE	CPT HCPCS	COVERAGE STATUS
(PN) for all indications		
Metatarsophalangeal Joint Replacement Implants: Ceramic prosthesis (e.g., Moje); or Modular implant (e.g., Metis); or Molded cylindrical implant (e.g., Cartiva SCI) for all indications and second Metatarsophalangeal joint replacement	No Specific Code L8641, L8642, L8658; L8699, 28899	Not Covered (Experimental/Investigational/Unproven)
NanoKnife surgery, or Irreversible Electroporation (IRE) - inoperable tumors in the pancreas, liver, prostate, and kidneys	55877, 47384	Not Covered (Experimental/Investigational/Unproven)
Nd: YAG laser vitreolysis (YAG Reflex Laser Systems, Ellex) - treatment of vitreous floaters or any other indication	No Specific Code 67031	Not covered (Experimental/Investigational/Unproven)
Nerve Hydrodissection procedure (e.g., Tarsal Tunnel tibial nerve compression) for all indications	No Specific Code 64450, 64999, 76942, 28999	Not covered (Experimental/Investigational/Unproven)
Oscillation and lung expansion device (e.g., BiWave Clear System) for all indications	No Specific Code E1399, E0469, A7021	Not Covered (Experimental/Investigation/Unproven)
OSSIOfiber Trimmable Nail System/Compression Screws - Orthopedic Surgeries fixation devices for all indications.	No Specific Code L8699	Not Covered (Experimental/Investigation/Unproven) **(May be included in surgical procedure)**
Platelet Rich Plasma for all indications (e.g., platelet-enriched plasma, platelet-rich concentrate) for all indications	P9020, G0460, G0465, 0232T	Not Covered (Experimental/Investigational/unproven)
Percutaneous electrical nerve field stimulation (PENFS) of the cranial nerves – functional abdominal pain for pediatric and adolescent patients (typically ages 8–21) (without implantation)	64567, 64999	Not Covered (Experimental/Investigational/Unproven)
Percutaneous Needled Tenotomy (PNT) for all indications	No Specific Code 27599, 20599	Not Covered (Experimental/Investigational/Unproven)

PROCEDURE	CPT HCPCS	COVERAGE STATUS
Pleximmune a specialized qualitative prognostic test (age group pediatrics less than 21 y/o) for acute cellular rejection in children with liver or intestine transplantation and all other indications	81560	Not Covered (Experimental/Investigational/Unproven)
Prescription Digital Therapeutics (PDT) (prescription-only software to manage medical disorders or diseases and cognitive and/or behavioral) (Multiple products)	No Specific Code T1505, A9291, A9292, G0552, G0553, G0554, A9294	Not Covered (Experimental/Investigational/Unproven)
Pudendal Nerve Blocks (Injections) (e.g., Chronic Pelvic Pain, Pudendal neuralgia (PN))	No Specific Code 64430	Not Covered (Experimental/Investigation/Unproven) **Note:** Does not apply to the use of pudendal nerve blocks in obstetrics and other operative pelvic procedures; considered bundle charges
Pulsed radiofrequency Denervation (for the treatment of various chronic pain syndromes) for all indications	No Specific Code 64999	Not Covered (Experimental/Investigation/Unproven)
Percutaneous Placement Permanent Common Carotid Embolic Protection Device	C8010	Not Covered (Experimental/Investigational/Unproven)
Radiofrequency Ablation (RFA) For Treatment Of Cervicogenic Headache	No Specific Code 64640	Not Covered (Experimental/Investigational/Unproven)
Relivion MG device for headaches and all other indications	E0733, A4541, E1399	Not Covered (Experimental/Investigational/Unproven)
Reverse Axillary Lymphatic Mapping - all indications	No Specific Code 38999, 38900	Not Covered (Experimental/Investigational/Unproven)
Skin Electronic Brachytherapy (eBx) - non-melanoma skin cancer (e.g., squamous cell and basal cell carcinoma)	77436, 77437, 77439,	Not Covered (Experimental/Investigational/Unproven)
Sphenopalatine Ganglion Nerve Block for any indication including, but may not be limited to, headaches and facial pain	64505	Not Covered (Experimental/Investigational/Unproven)

PROCEDURE	CPT HCPCS	COVERAGE STATUS
Surface Radiation Therapy (SRT) - non-melanoma skin cancer (e.g., squamous cell and basal cell carcinoma)	77436, 77437, 77438, 77439, 77336	Not Covered (Experimental/Investigational/Unproven)
TenoTac® Soft Tissue Fixation System for all indications	No Specific Code 28285	Not Covered (Experimental/Investigational/Unproven)
Topaz Coblation Therapy, (Radiofrequency coblation tenotomy) for all indications	No Specific Code 28899, 20999	Not Covered (Experimental/Investigational/Unproven)
Topographic Brain Mapping, quantitative EEG (qEEG) brain mapping for all behavioral health indication (e.g. including ADHD, depression, and learning disabilities)	S8040	Not Covered (Experimental/Investigational/Unproven)
Trabecular Bone Score (TBS) Bone Mineral Density Measurement) to Predict Fracture Risk (e.g., Osteoporosis) in Postmenopausal Patients	77089, 77090, 77091, 77092	Not Covered (Experimental/Investigational/Unproven)
Trigeminal nerve blocks for Trigeminal Neuralgia; Cluster Headaches, Migraines and other facial pain	No Specific Code 64400	Not Covered (Experimental/Investigational/Unproven)
Vaporous Hyperoxia Therapy (VHT) (chronic and hard-to-heal wounds)	97610	Not Covered (Experimental/Investigational/Unproven)
Vascular Lymph Node Transfer (VLNT) also called lymph node transfer (LNT) for all indications	No Specific Code 38999, 38308,	Not Covered (Experimental/Investigational/Unproven)
Virtual Reality Cognitive Behavioral Health therapy device for all indications	E1905	Not Covered (Experimental/Investigational/Unproven)
Whole body vibration (WBV) therapy (e.g., Galileo Plate Device) for all indications	No Specific Code 97110, 97112, 97139, 97530, E1399	Not Covered (Experimental/Investigational/Unproven)

Definitions

Experimental, Investigational, or Unproven - Medical and behavioral healthcare procedures, pharmaceuticals, and devices (collectively “technologies”) where peer-reviewed and evidence-based literature indicates the technology remains under scientific review, is not in general use or a community standard, has not been found to be safe and efficacious, and has not been shown to have a demonstratable benefit.

Related Policies

Category III Current Procedural Terminology (CPT) Codes

Clinical Resources Used for Medical Necessity Determinations When No Other UM Clinical Criteria or Guideline Exists

Medical Necessity Reviews

Proprietary Laboratory Codes (PLA)

Utilization Management Clinician Determinations of Non-coverage

Appendix

Policy Number:

Effective: 1/1/2021 **Next review:** 3/1/2027

Policy type: Enterprise

Author(s):

Depts.: Health Services

Applicable regulation(s): Social Security Act Section §1862(a), 42 CFR 411.15(o), NCQA UM 10(A)(B) – Evaluation of New Technology; Excluded Services Guideline E1 and E2 of the OHP Prioritized List of Health Services for guidance on New and Emerging Technology; OAR 410-120-1200; WAC 284-44-043, WAC 284-46-507, IDS 41-3930, 41-5903, MCA 33-32-103, ARM 37.82.102(c).

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