New and Emerging Technology - Coverage Status

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

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 84112reflect 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 and 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
    - Report on long term studies indicating improved health outcomes and clinical trials now recruiting or in process

- Information available from evidence-based resources may vary depending on treatment procedure or device. The evidenced-based resources, which relies on the judgment of experts, include the following resources, with additional resources reviewed as necessary based on the technology being reviewed:
    - Agency for Healthcare Research and Quality (AHRQ)
    - Carelon Medical Benefits Management Clinical Guidelines, formerly AIM (AIM Specialty Health) Clinical Guidelines
    - Alliance of Community Health Plans (ACHP)
    - American College of Radiology® (ACR)
    - American Hospital Formulary Service Drug Information (AHFS® DI™)
    - Bree Collaborative – Foundation for Health Care Quality
    - Centers for Disease Control and Prevention (CDC)
    - Cochrane Collaboration
    - Facts and Comparison®
    - Hayes, Inc., and Hayes Genetic Testing Evaluation Service
    - MCG Health
    - MEDLINE® (component of PubMed®
    - Micromedex®
    - National Comprehensive Cancer Network® (NCCN)
    - National Institute for Health and Care Excellence (NICE)
    - Oregon Health Evidence Review Commission (HERC)
    - Professional Societies Recommendations and Practice Guidelines
    - UpToDate®
    - U.S. Pharmacopeia Dispensing Information
    - Washington Health Technology Assessment (HTA)
    - Washington Health Technology Clinical Committee (HTCC)
- Survey of similar market carriers and their published coverage position and/or medical policy concerning the service of technology under review
- 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 the 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 one of two options:

- Covered service, which may include developing specific clinical guidelines criteria
- Deemed experimental, investigational, or unproven (E/I/U) and 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 be indicated for archival (i.e., remains unproven but only requires a review upon request) 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 demonstratable benefit or been shown to be safe and efficacious
    - Claims utilization indicates PacificSource has not received a request for a period of at least two years
- The unproven technology which has been determined to be archivable, will be moved to an excel sheet (NTOC Agenda Review Schedule) on the Special Function SharePoint site and noted as archived in the modification history along with associated codes

Quality Oversight

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

In addition, 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 Guideline Notes 172 and 173 of the OHP Prioritized List of Health Services for guidance on New and Emerging Technology. In the absence of OHP guidance, PCS will follow this policy.

Medicare

PacificSource Medicare follows CMS guidelines and criteria. In the absence of CMS guidelines and criteria, PacificSource Medicare will follow internal policy for determination of coverage and medical necessity.

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 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 (Auricle Acupuncture) treatment for prevention, treatment, and harm reduction of substance use.	No Specific Code 97810 97811	Not Covered (Experimental/Investigational/Unproven) (Refer to Contract for coverage as well)
Allogeneic haemopoietic stem cell transplantation (HSCT) for Crohn's Disease	No Specific Code 38240	Not Covered (Experimental/Investigational/Unproven)
Artificial Iris (Custom Flex) for the Treatment of Aniridia (e.g. Custom Flex Artificial Iris)	66999 66683	Not Covered (Experimental/Investigational/Unproven)
Cala Trio (Cala Health, Inc.) for Treatment of Essential Tremor – (also referred to as transcutaneous afferent patterned stimulation (TAPS)) (e.g.; Cala One and Cala Trio)	E0734; A4542	Not Covered (Experimental/Investigational/Unproven)
Chromoendoscopy (In vivo analysis) , (also known as chromoscopy and chromocolonoscopy) for all indications,	No Specific Code 44799, 45399, 45999	Not Covered (Experimental/Investigational/Unproven)
Coil embolization of hemorrhoids (Emborrhoid technique) embolization of the hemorrhoidal arteries.	No Specific Code 37241, 37244	Not Covered (Experimental/Investigational/Unproven)
Continuous Passive Motion (CPM) for Knees and all other indications	E0935, E0936	Not Covered (Experimental/Investigational/Unproven) (Legacy Employee Health Plan covers for knees)
Cryoablation for chronic rhinitis (allergic or nonallergic) (e.g., ClariFix device)	No Specific Code 31243	Not Covered (Experimental/Investigational/Unproven)
Cranial Electrotherapy Stimulation (CES), also known as cranial electrical stimulation, transcranial electrical stimulation (e.g., Alpha Stim Device, CES Ultra) for all indications	E0732, A4596	Not Covered (Experimental/Investigational/Unproven)

PROCEDURE	CPT HCPCS	COVERAGE STATUS
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 **HCPC Codes:** L8680 L8685 L8686 L8687 L8688	Not Covered (Experimental, Investigational/Unproven)
DISC Nucleoplasty (Radiofrequency Coblation) a percutaneous disc decompression (PDD) or radiofrequency coblation -used to treat herniated discs (e.g., ArthroCare System, Per-D Spine Wand)	S2348	Not Covered (Experimental, Investigational/Unproven)
EarliPoint™ Evaluation - diagnosing and assessing autism in children 16 to 30 months old	No specific Code 97110 97112	Not Covered (Experimental/Investigational/Unproven)
Erector Spinae Pain block (ESP block) for all indications	No Specific Code 64999	Not Covered (Experimental/Investigational/Unproven)
Esophageal cooling device (e.g.; ensoETM) for all indications	No Specific Code 43499	Not Covered (Experimental/Investigational/Unproven)
External Trigeminal Nerve Stimulation (eTNS) System (e.g. Monarch; NeuroSigma) indication ADHD in children aged 7 to 12 years	E0733 A4541	Not Covered (Experimental/Investigational/Unproven)
Extracorporeal shock wave therapy (ESWT),	28890	Not Covered (Experimental/Investigational/Unproven)
Gait Analysis (computerized) (Motion Analysis) for all indications.	96000, 96001	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)
Geniculate artery embolization (GAE) (embolization of the knee) – treatment of osteoarthritis related knee pain	No Specific Code 37242	Not Covered (Experimental/Investigational/Unproven) **Approved** for coverage of knee hemarthrosis

PROCEDURE	CPT HCPCS	COVERAGE STATUS
Genova's GI Effects Comprehensive Profile analyzes for all indications	No Specific Code 81599, 89240, 81479	Not Covered (Experimental;/investigational/Unproven)
Implantable shock absorber (e.g., MISHA knee system) for all indications	No Specific Code L8699 27599	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)
Interferential Current Stimulation Therapy (IFS/ICT) (electrical stimulation) for all indications.	S8130, S8131	Not Covered (Experimental/Investigational/Unproven)
Intra-arterial Infusion (Embolization) of imipenem/cilastatin sodium (IPM/CS) refractory interphalangeal (DIP) joint-Osteoarthritis (OA) and all other indications.	No Specific Code 37242 20999	Not Covered (Experimental/Investigational/Unproven)
Intravascular Lithotripsy (IVL) – (Shockwave intravascular lithotripsy system (IVL)) Coronary	92972	Not Covered (Experimental/Investigational/Unproven)
iovera (Pacira Biosciences Inc.) System (cold injection) for Knee Osteoarthritis	No Specific Code 64640,	Not Covered (Experimental/Investigational/Unproven)
Jaw Motion Rehab System--(e.g., TheraBite Jaw Motion Rehabilitation System, OraStretch press, and Dynasplint Trismus System) – all indications	E1700, E1701, E1702	Not Covered (Experimental/Investigational/Unproven)
Latera Nasal Implant (Absorbable nasal implants) for all indications	No Specific Code 30999 30468	Not Covered (Experimental/Investigational/Unproven)
LipiView II and LipiScan Ocular Surface Interferometer images with Dynamic Meibomian Imaging (DMI)	No Specific Code 92285	Not Covered (Experimental/Investigational/Unproven) **Refer to Category III policy for "T" codes**

PROCEDURE	CPT HCPCS	COVERAGE STATUS
Lymphaticovenous Anastomosis (LVA) (Lymphovenous bypass or shunt) for lymphedema	No Specific Code 38999, 38308	Not Covered (Experimental/Investigational/Unproven)
Magnetic Resonance Neurography (MRN), (also known as Magnetic Resonance Neurogram or MR Imaging of the Peripheral Nerves (PNI)) for all indications	No Specific Code 76498	Not Covered (Experimental/Investigation/Unproven) (Carelon does not review)
MiraDry System aka Microwave or electromagnetic energy (microwave thermolysis) for all indications of hyperhidrosis	No Specific Code 17999	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, 67299	Not Covered (Experimental/Investigational/Unproven)
Navigated transcranial magnetic stimulation (nTMS) - presurgical planning	No Specific Code 64999	Not covered (Experimental/Investigational/Unproven)
Non-Pneumatic Active Dynamic Compression (Dayspring (Koya Medical Inc.)) for Treatment of Lymphedema	No Specific Code E0678, E0679, E0680, E0681, E0682	
Occipital Nerve Stimulation (ONS) - intended to prevent migraines headaches and all other headaches	No Specific Code 64553; 61885; 61886; 64999	Not Covered (Experimental/Investigational/Unproven)
Occipital Nerve Decompression Surgery (ONS) (Also known as Peripheral Occipital nerve decompression surgery or migraine surgery) for Migraine Headaches	No Specific Code 64716, 64722, 64999, 64640	Not Covered (Experimental/Investigational/Unproven)
Oscillation and lung expansion device (e.g. Volara System, BiWave Clear System) for all indications	No Specific Code E1399, E0469, A7021	Not Covered (Experimental/Investigation/Unproven) **Note**: Volara System FDA recall 7/16/2024.
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)

PROCEDURE	CPT HCPCS	COVERAGE STATUS
Ovarian or Internal Iliac Vein Embolization for Treatment of Pelvic Congestion Syndrome	No Specific Code 37241	Not Covered (Experimental/Investigational/unproven)
Patency Capsule Testing (e.g., PillCam Patency System, Agile Patency System/Capsule) for all indications	No specific code, 91299	Not Covered (Experimental/Investigational/Unproven)
Percutaneous ultrasonic ablation (e.g., Tenex percutaneous ultrasonic ablation procedures) - for all indications	No Specific Code 20999, 27599, 17999, 25999, 24999	Not Covered (Experimental/Investigational/Unproven) (May be coded depending on the area of treatment)
Percutaneous electrical nerve stimulation (PENS)/percutaneous neuromodulation therapy (PNT) all indications (e.g., chronic musculoskeletal or neuropathic pain)	No specific code 64999	Not Covered (Experimental/Investigational/Unproven)
Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)	92972	Not Covered (Experimental/Investigational/Unproven)
PortableConnect/ ROMTech (ROMTech Portable Connect Rehab Adaptive Device) (e.g., postsurgical rehabilitative exercises) for all indications	No Specific Code E1399	Not Covered (Experimental/Investigational/Unproven)
Prescription Digital Therapeutics (PDT) (prescription-only software to manage medical disorders or diseases)	No Specific Code 99199, E1399, T1505, A9291, A9999, A9292	Not Covered (Experimental/Investigational/Unproven)
Pudendal Nerve Blocks (Injections) (e.g.; Chronic Pelvic Pain, Pudendal neuralgia (PN))	64430	Not Covered (Experimental/Investigation/Unproven) **Note:** Does not apply to the use of pudendal nerve blocks in obstetrics and other operative pelvic procedures;
Radiofrequency Intradiscal Biacuplasty (IBD) (e.g., Bialys TransDiscal System or Biacuplasty) (referred to as (TIPs)) for all indications	No Specific Code 22899	Not Covered (Experimental/Investigational/Unproven)

PROCEDURE	CPT HCPCS	COVERAGE STATUS
Radiofrequency Nasal Valve w/VivAer Device – Treatment of nasal airway obstruction	30469	Not Covered (Experimental/Investigational/Unproven)
Reflectance confocal microscopy (RCM) (Confocal laser scanning microscopy) for skin lesion surveillance	96931, 96932, 96933, 96934, 96935, 96936	Not Covered (Experimental/Investigational/Unproven)
Reverse Axillary Lymphatic Mapping - all indications	No Specific Code 38999, 38900	Not Covered (Experimental/Investigational/Unproven)
RhinAer Procedure (Aerin Medical) (posterior nasal nerve ablation using radiofrequency) for Treatment of Chronic Rhinitis	No Specific Code 31242 30999	Not Covered (Experimental/Investigational/Unproven
Robotic Assisted In-Home Therapy Device/ Systems (e.g. Motus Hand/Foot Robotic System, IpsilHand) for all indications	E0739; E0738	Not Covered (Experimental/Investigational/Unproven)
Selective Myectomy for all indications	No Specific Code 21499	Not Covered (Experimental/Investigational/Unproven)
Sphenopalatine Ganglion Nerve Block for any indication including, but may not be limited to, headaches or trigeminal neuralgia.	No Specific Code 64505	Not Covered (Experimental/Investigational/Unproven)
Subacromial Balloon Spacer Implantation (InSpace) Rotator cuff repair or any other indication	No Specific Code 29999, C9781	Not Covered (Experimental/Investigational/Unproven)
Supraorbital Nerve Block Injection w/Ultrasound (SON) - for all indications (e.g., Migraine Headaches suboccipital neuralgia)	No Specific Code 64400 64999	Not Covered (Experimental/Investigational/Unproven)
Thermal Capsular Shrinkage Therapy (e.g.; Thermal capsulorrhaphy or Electrothermal Shrinkage) for all orthopedic indications	No Specific Code 29999, S2300, 25320	Not Covered (Experimental/Investigational/Unproven)
Trabecular Bone Score (TBS) Bone Mineral Density Measurement) to Predict Fracture Risk in Postmenopausal Patients	77089, 77090, 77091, 77092	Not Covered (Experimental/Investigational/Unproven)
Transcutaneous Vagal Nerve Stimulator (t-VNS) and Vagus	E0735	Not Covered (Experimental/Investigational/Unproven)

PROCEDURE	CPT HCPCS	COVERAGE STATUS
Nerve Stimulation (VNS non-implantable) (e.g., depression/Bipolar/psychological disorders and all other indications)		
Vagus Nerve Stimulation (Non-implantable, noninvasive tVNS, gammaCore Sapphire Device) for cluster and migraine headaches	E0735	Not Covered (Experimental/Investigation/Unproven)
Vascular Lymph Node Transfer (VLNT) also called lymph node transfer (LNT); Lymphatic By-pass Procedure) for all indications	No Specific Code 38999, 38308	Not Covered (Experimental/Investigational/Unproven)
Vertebral axial decompression (e.g., Lordex; VAX-D; DRX, and DRS System), (mechanized spinal distraction therapy or non-surgical traction device) for back pain	S9090	Not Covered (Experimental/Investigational/Unproven)
Virtual Reality Cognitive Behavioral Health therapy device	E1905	Not Covered (Experimental/Investigational/Unproven) (All "T" code related to Virtual Reality denied per Category III Policy)
Whole Body Vibration Platform (Galileo Plate) for all indications	No Specific Code E1399	Not Covered (Experimental/Investigational/Unproven)
Wireless GI Motility Monitoring Capsule Testing (e.g., SmartPill Mobility Testing System) – for all indications	91112	Not Covered (Experimental/Investigational/Unproven)

Related Policies

Category III Current Procedural Terminology (CPT) Codes

Medical Necessity Reviews

Appendix

Policy Number:

Effective: 1/1/2021 **Next review:** 2/1/2025

Policy type: Enterprise

Author(s):

Depts.: Health Services

Applicable regulation(s): NC Social Security Act Section §1862 (a), 42 CFR 411.15(o), NCQA UM 10(A)(B) – Evaluation of New Technology; Guideline Notes 172 and 173 of the OHP Prioritized List of Health Services for guidance on New and Emerging Technology; WAC 284-44-043, WAC 284-46-507, IDS 41-3930, 41-5903, MCA 33-32-103, ARM 37.82.102(c)QA UM 10(A)(B) – Evaluation of New Technology; Guideline Notes 172 and 173 of the OHP Prioritized List of Health Services for guidance on New and Emerging Technology; WAC 284-44-043, WAC 284-46-507, IDS 41-3930, 41-5903, MCA 33-32-1003, ARM 37.82.102(c)

Commercial OPs: 12/2024

Government OPs: 1/2025