





### **Medical Coverage Policy and Prior Authorization Update Notice**

Publication date: 10/1/2023

The following medical coverage policies are either new policies, or policies that have completed their annual review. The second column provides significant information regarding content change that might be of importance to you. The effective date for Policy changes will be 11/1/2023 except as noted with\* where the effective date will be 10/01/2023.

SWHP Policy	Change
None	None

#### **Notice:**

New to market medical specialty drugs may require prior authorization. This includes new medical drugs with a drug specific Healthcare Common Procedure Coding System (HCPCS) code as well as drugs with a miscellaneous HCPCS code. Please note inclusion of a drug in this update document does not guarantee benefit coverage. You should verify benefits prior to requesting authorization. Payment for authorized services is contingent upon verification of eligibility for benefits, the benefits available in the member's plan, the applicable contractual limitations, restrictions and exclusions.

### Prior Authorization List changes (all plans except Medicaid) effective 9/1/2023

Code	Category: Description	Action	Plans
	NOTE: All of the following additions are potentially		
	"Experimental, Investigational, or Unproven"		
81449	Targeted genomic sequence analysis panel, solid organ neoplasm, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, MET, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed; RNA analysis	Add	All Plans
81451	Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NOTCH1, NPM1, NRAS), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis	Add	All Plans
81456	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm or disorder, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MET, MLL, NOTCH1, NPM1, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis	Add	All Plans
0364U	Services and devices considered experimental/investigational/unproven: Oncology (hematolymphoid neoplasm), genomic sequence analysis using multiplex (PCR) and next-generation sequencing with algorithm, quantification of dominant clonal sequence(s), reported as presence or absence of minimal residual disease (MRD) with quantitation of disease burden, when appropriate	Add	All Plans
0365U	Services and devices considered experimental/investigational/unproven: Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of bladder cancer	Add	All Plans
0366U	Services and devices considered experimental/investigational/unproven: Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of recurrent bladder cancer	Add	All Plans
0367U	Services and devices considered experimental/investigational/unproven: Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, diagnostic algorithm reported as a risk score for probability of rapid recurrence of recurrent or persistent cancer following transurethral resection	Add	All Plans
0368U	Services and devices considered experimental/investigational/unproven: Oncology (colorectal cancer), evaluation for mutations of APC, BRAF, CTNNB1, KRAS, NRAS, PIK3CA, SMAD4, and TP53, and methylation markers (MYO1G, KCNQ5, C9ORF50, FLI1, CLIP4, ZNF132 and TWIST1), multiplex quantitative polymerase chain reaction (qPCR), circulating cell-free DNA (cfDNA), plasma, report of risk score for advanced adenoma or colorectal	Add	All Plans
0375U	Services and devices considered experimental/investigational/unproven: Oncology (ovarian), biochemical assays of 7 proteins (follicle stimulating hormone, human epididymis protein 4, apolipoprotein A-1, transferrin, beta-2 macroglobulin, prealbumin [ie, transthyretin], and cancer antigen 125), algorithm reported as ovarian cancer risk score	Add	All Plans
0376U	Services and devices considered experimental/investigational/unproven: Oncology (prostate cancer), image analysis of at least 128 histologic features and clinical factors, prognostic algorithm determining the risk of distant metastases, and prostate cancerspecific mortality, includes predictive algorithm to androgen deprivation-therapy response, if appropriate	Add	All Plans
0377U	Services and devices considered experimental/investigational/unproven: Cardiovascular disease, quantification of advanced serum or plasma lipoprotein profile, by nuclear magnetic resonance (NMR) spectrometry with report of a lipoprotein profile (including 23 variables)	Add	All Plans
0378U	Services and devices considered experimental/investigational/unproven: RFC1 (replication factor C subunit 1), repeat expansion variant analysis by traditional and repeat-primed PCR, blood, saliva, or buccal swab	Add	All Plans

0379U	Services and devices considered experimental/investigational/unproven: Targeted genomic sequence analysis panel, solid organ neoplasm, DNA (523 genes) and RNA (55 genes) by next-generation sequencing, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutational burden	Add	All Plans
0380U	Services and devices considered experimental/investigational/unproven: Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis, 20 gene variants and CYP2D6 deletion or duplication analysis with reported genotype and phenotype	Add	All Plans
0381U	Services and devices considered experimental/investigational/unproven: Maple syrup urine disease monitoring by patient-collected blood card sample, quantitative measurement of allo-isoleucine, leucine, isoleucine, and valine, liquid chromatography with tandem mass spectrometry (LC-MS/MS)	Add	All Plans
0382U	Services and devices considered experimental/investigational/unproven: Hyperphenylalaninemia monitoring by patient-collected blood card sample, quantitative measurement of phenylalanine and tyrosine, liquid chromatography with tandem mass spectrometry (LC-MS/MS)	Add	All Plans
0383U	Services and devices considered experimental/investigational/unproven: Tyrosinemia type I monitoring by patient-collected blood card sample, quantitative measurement of tyrosine, phenylalanine, methionine, succinylacetone, nitisinone, liquid chromatography with tandem mass spectrometry (LC-MS/MS)	Add	All Plans
0384U	Services and devices considered experimental/investigational/unproven: Nephrology (chronic kidney disease), carboxymethyllysine, methylglyoxal hydroimidazolone, and carboxyethyl lysine by liquid chromatography with tandem mass spectrometry (LC-MS/MS) and HbA1c and estimated glomerular filtration rate (GFR), with risk score reported for predictive progression to high-stage kidney disease	Add	All Plans
0385U	Services and devices considered experimental/investigational/unproven: Nephrology (chronic kidney disease), apolipoprotein A4 (ApoA4), CD5 antigen-like (CD5L), and insulin-like growth factor binding protein 3 (IGFBP3) by enzyme-linked immunoassay (ELISA), plasma, algorithm combining results with HDL, estimated glomerular filtration rate (GFR) and clinical data reported as a risk score for developing diabetic kidney disease	Add	All Plans
0386U	Services and devices considered experimental/investigational/unproven: Gastroenterology (Barrett's esophagus), P16, RUNX3, HPP1, and FBN1 methylation analysis, prognostic and predictive algorithm reported as a risk score for progression to high-grade dysplasia or esophageal cancer	Add	All Plans

## Prior Authorization List changes (all plans except Medicaid) Effective 10/01/2023

Code	Category: Description	Action	Plans
J2781	Injection, pegcetacoplan, intravitreal, 1mg	Add	All Plans
J7214	Injection, factor viii/von willebrand factor complex, recombinant, per factor viii i.u.	Add	All Plans
J9051	Injection, bortezomib, 0.1mg	Add	All Plans
J9064	Injection, cabazitaxel, 1mg	Add	All Plans
J9345	Injection, retifanlimab-dlwr, 1mg	Add	All Plans
	NOTE: All of the following additions are potentially "Experimental, Investigational, or Unproven"		
0387U	Services and devices considered experimental/investigational/unproven: Oncology (non-small cell lung cancer), next-generation sequencing with identification of single nucleotide variants, copy number variants, insertions and deletions, and structural variants in 37 cancer-related genes, plasma, with report for alteration detection	Add	All Plans
0388U	Services and devices considered experimental/investigational/unproven: Pediatric febrile illness (Kawasaki disease [KD]), interferon alpha-inducible protein 27 (IFI27) and mast cell-expressed membrane protein 1 (MCEMP1), RNA, using reverse transcription polymerase chain reaction (RT-qPCR), blood, reported as a risk score for KD	Add	All Plans

0389U	Services and devices considered experimental/investigational/unproven: Obstetrics (preeclampsia), kinase insert domain receptor (KDR), Endoglin (ENG), and retinol-binding protein 4 (RBP4), by immunoassay, serum, algorithm reported as a risk score	Add	All Plans
0390U	Services and devices considered experimental/investigational/unproven: Oncology (solid tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffinembedded (FFPE) tissue, 437 genes, interpretive report for single nucleotide variants, splice-site variants, insertions/deletions, copy number alterations, gene fusions, tumor mutational burden, and microsatellite instability, with algorithm quantifying immunotherapy response score	Add	All Plans
0391U	Services and devices considered experimental/investigational/unproven: Drug metabolism (depression, anxiety, attention deficit hyperactivity disorder [ADHD]), gene-drug interactions, variant analysis of 16 genes, including deletion/duplication analysis of CYP2D6, reported as impact of gene-drug interaction for each drug	Add	All Plans
0392U	Services and devices considered experimental/investigational/unproven: Neurology (eg, Parkinson disease, dementia with Lewy bodies), cerebrospinal fluid (CSF), detection of misfolded a-synuclein protein by seed amplification assay, qualitative	Add	All Plans
0393U	Services and devices considered experimental/investigational/unproven: Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 16 PFAS compounds by liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma or serum, quantitative	Add	All Plans
0394U	Services and devices considered experimental/investigational/unproven: Oncology (lung), multi-omics (microbial DNA by shotgun next-generation sequencing and carcinoembryonic antigen and osteopontin by immunoassay), plasma, algorithm reported as malignancy risk for lung nodules in early-stage disease	Add	All Plans
0395U	Services and devices considered experimental/investigational/unproven: Obstetrics (pre- implantation genetic testing), evaluation of 300000 DNA single-nucleotide polymorphisms (SNPs) by microarray, embryonic tissue, algorithm reported as a probability for single-gene germline conditions	Add	All Plans
0396U	Services and devices considered experimental/investigational/unproven: Oncology (non-small cell lung cancer), cell-free DNA from plasma, targeted sequence analysis of at least 109 genes, including sequence variants, substitutions, insertions, deletions, select rearrangements, and copy number variations	Add	All Plans
0397U	Services and devices considered experimental/investigational/unproven: Gastroenterology (Barrett esophagus), P16, RUNX3, HPP1, and FBN1 DNA methylation analysis using PCR, formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as risk score for progression to high-grade dysplasia or cancer	Add	All Plans
0398U	Services and devices considered experimental/investigational/unproven: Neurology (cerebral folate deficiency), serum, detection of anti-human folate receptor IgG-binding antibody and blocking autoantibodies by enzyme-linked immunoassay (ELISA), qualitative, and blocking autoantibodies, using a functional blocking assay for IgG or IgM, quantitative, reported as positive or not detected	Add	All Plans
0399U	Services and devices considered experimental/investigational/unproven: Obstetrics (expanded carrier screening), 145 genes by nextgeneration sequencing, fragment analysis and multiplex ligationdependent probe amplification, DNA, reported as carrier positive or negative	Add	All Plans
0400U	Services and devices considered experimental/investigational/unproven: Cardiology (coronary heart disease [CAD]), 9 genes (12 variants), targeted variant genotyping, blood, saliva, or buccal swab, algorithm reported as a genetic risk score for a coronary event	Add	All Plans
0401U	Services and devices considered experimental/investigational/unproven: Motor- cognitive, semi-immersive virtual reality-facilitated gait training, each 15 minutes (List separately in addition to code for primary procedure)	Add	All Plans
0791T	Services and devices considered experimental/investigational/unproven: Application of silver diamine fluoride 38%, by a physician or other qualified health care professional	Add	All Plans
0792T	Services and devices considered experimental/investigational/unproven: Percutaneous transcatheter thermal ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance	Add	All Plans

	Services and devices considered experimental/investigational/unproven: Patient- specific, assistive, rules-based algorithm for ranking pharmaco-oncologic treatment options based on the patient's tumor-specific cancer marker information obtained from prior molecular	Add	All Plans
0793T	pathology, immunohistochemical, or other pathology results which have been previously interpreted and reported separately		
0794T	Services and devices considered experimental/investigational/unproven: Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; complete system (ie, right atrial and right ventricular pacemaker components)	Add	All Plans
0795T	Services and devices considered experimental/investigational/unproven: Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component (when an existing right ventricular single leadless pacemaker exists to create a dual-chamber leadless pacemaker system)	Add	All Plans
0796Т	Services and devices considered experimental/investigational/unproven: Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	Add	All Plans
0797T	Services and devices considered experimental/investigational/unproven: Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; complete system (ie, right atrial and right ventricular pacemaker components)	Add	All Plans
0798T	Services and devices considered experimental/investigational/unproven: Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right atrial pacemaker component	Add	All Plans
0799T	Services and devices considered experimental/investigational/unproven: Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	Add	All Plans
0800T	Services and devices considered experimental/investigational/unproven: Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; dual-chamber system (ie, right atrial and right ventricular pacemaker components)	Add	All Plans
0801T	Services and devices considered experimental/investigational/unproven: Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component	Add	All Plans
0802T	Services and devices considered experimental/investigational/unproven: Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	Add	All Plans
0803T	Services and devices considered experimental/investigational/unproven: Programming device evaluation (in person) with iterative adjustment of implantable device to test the function of device and to select optimal permanent programmed values, with analysis, review, and report, by a physician or other qualified health care professional, leadless pacemaker system in dual cardiac chambers	Add	All Plans
0804T	Services and devices considered experimental/investigational/unproven: Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); percutaneous femoral vein approach	Add	All Plans

0805T	Services and devices considered experimental/investigational/unproven: Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); open femoral vein approach	Add	All Plans
0806T	Services and devices considered experimental/investigational/unproven: Pulmonary tissue ventilation analysis using software-based processing of data from separately captured cinefluorograph images; in combination with previously acquired computed tomography (CT) images, including data preparation and transmission, quantification of pulmonary tissue ventilation, data review, interpretation and report	Add	All Plans
0807T	Services and devices considered experimental/investigational/unproven: Pulmonary tissue ventilation analysis using software-based processing of data from separately captured cinefluorograph images; in combination with computed tomography (CT) images taken for the purpose of pulmonary tissue ventilation analysis, including data preparation and transmission, quantification of pulmonary tissue ventilation, data review, interpretation and report	Add	All Plans
0808T	Services and devices considered experimental/investigational/unproven: Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, placement of transfixing device(s) and intra-articular implant(s), including allograft or synthetic device(s)	Add	All Plans
0809T	Services and devices considered experimental/investigational/unproven: Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies	Add	All Plans
0810T	Services and devices considered experimental/investigational/unproven: Oncology (non-small cell lung cancer), next-generation sequencing with identification of single nucleotide variants, copy number variants, insertions and deletions, and structural variants in 37 cancer-related genes, plasma, with report for alteration detection	Add	All Plans

# SECOND NOTICE Prior Authorization List changes (all plans except Medicaid) Effective 11/01/2023

Code	Category: Description	Action	Plans
J0174	Injection, lecanemab-irmb, 1 mg	Add	All Plans
	NOTE: All of the following additions are potentially		
	"Experimental, Investigational, or Unproven"		
0001U	Red blood cell antigen typing, DNA, human erythrocyte antigen gene analysis of 35 antigens from 11 blood groups	Remove	Medicare Plans only
0119U	Cardiology, ceramides by liquid chromatography-tandem mass spectrometry, plasma, quantitative report with risk score for major cardiovascular events	Remove	Medicare Plans only
0193U	Red cell antigen (JR blood group) genotyping (JR), gene analysis, ABCG2 (ATP binding cassette subfamily G member 2 [Junior blood group]) exons 2-26	Remove	Medicare Plans only
0229U	BCAT1 (Branched chain amino acid transaminase 1) and IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis	Remove	Medicare Plans only
0237U	Genetic/genomic testing: CEP72 (centrosomal protein, 72-KDa), NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis	Change from E&I to standard PA	Medicare Plans only
0245U	Genetic/genomic testing: Oncology (thyroid), mutation analysis of 10 genes and 37 RNA fusions and expression of 4 mRNA markers using next-generation sequencing, fine needle aspirate, report includes associated risk of malignancy expressed as a percentage	Change from E&I to standard PA	Medicare Plans only
0286U	Genetic/genomic testing: CEP72 (centrosomal protein, 72-KDa), NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis	Change from E&I to standard PA	Medicare Plans only
0287U	Genetic/genomic testing: Oncology (thyroid), DNA and mRNA, next-generation sequencing analysis of 112 genes, fine needle aspirate or formalin-fixed paraffin-embedded (FFPE) tissue, algorithmic prediction of cancer recurrence, reported as a categorical risk result	Change from E&I to standard PA	Medicare Plans only

81231	CYP3A5 (cytochrome P450 family 3 subfamily A member 5) (eg, drug metabolism), gene analysis, common variants	Change from E&I to standard PA	Medicare Plans only
81355	VKORC1 (vitamin K epoxide reductase complex, subunit 1) (eg, warfarin metabolism), gene analysis, common variant(s)	Remove	Medicare Plans only
81418	Drug metabolism (eg, pharmacogenomics) genomic sequence analysis panel, must include testing of at least 6 genes, including CYP2C19, CYP2D6, and CYP2D6 duplication/deletion analysis	Change from E&I to standard PA	Medicare Plans only

# FIRST NOTICE Prior Authorization List changes (all plans except Medicaid) effective 12/01/2023 (60-Day Notice)

Code	Category: Description	Action	Plans
A4239	Continuous Glucose Monitoring: Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1-month supply	Add	Medicare Plans only
J0349	Injection, rezafungin, 1mg	Add	All Plans
J7353	Topical, anacaulase-bcdb, 8.8% gel, 1 gm	Add	All Plans
	NOTE: All of the following additions are potentially "Experimental, Investigational, or Unproven"		
A4575	Topical hyperbaric oxygen chamber, disposable.	Add	Commercial and Medicare Plans
E0446	Topical oxygen delivery system	Add	Commercial and Medicare Plans
S8940	Equestrian/hippotherapy, per session	Add	Commercial and Medicare Plans
	NOTE: The following additions are for pharmaceuticals currently using miscellanous codes which will be updated as HCPCS code(s) change		
C9399 J9999	Injection, glofitamab-gxbm	Add	All Plans
C9399 J3590	Injection, delandistrogene moxeparvovec-rokl	Add	All Plans
C9399 J3590	Injection, valoctocogene roxaparvovec-rvox	Add	All Plans
C9399 J3590	Injection, rozanolixizumab-noli	Add	All Plans
C9399 J9999	Injection, elranatamab-bcmm	Add	All Plans
C9399 J3590	Injection, aflibercept	Add	All Plans
C9399 J3490	Injection, avacincaptad pegol	Add	All Plans
C9399 J3590	Injection, somatrogon-ghla	Add	All Plans
C9399 J9999	Injection, talquetamab-tgvs	Add	All Plans
C9399 J3590	Injection, pozelimab-bbfg	Add	All Plans

### Prior Authorization List changes for Medicaid and CHIP

Code	Description	Action	Effective Date
J9345	Injection, retifanlimab-dlwr, 1mg	Add	10/1/23
J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose	Add	11/1/23
J0174	Injection, lecanemab-irmb, 1 mg	Add	11/1/23
A4575	Topical hyperbaric oxygen chamber, disposable.	Add	12/1/23
E0446	Topical oxygen delivery system	Add	12/1/23

#### **Additional Information for Providers**

The rendering provider must be the same on the preauthorization request and on the claim's submission. If there is a change, it is imperative that the utilization review team is notified to amend the preauthorization in a timely manner.

<u>Click here</u> to access last month's medical Coverage Policy and Prior Authorization Update Notice.

As always, we welcome your comments. You can reach us at: <a href="https://example.com/HPMedicalDirectors@BSWHealth.org">HPMedicalDirectors@BSWHealth.org</a>
<a href="mailto:BSWHPMedicalDirectors@BSWHealth.org">BSWHPMedicalDirectors@BSWHealth.org</a>