

US Family Health Plan

Table of Contents		Page Number
I.	<a href="#">ACTION</a>	1
II.	<a href="#">POLICY DISCLAIMER</a>	1
III.	<a href="#">POLICY</a>	1
IV.	<a href="#">SCOPE</a>	2
V.	<a href="#">POLICY CRITERIA</a>	2
VI.	<a href="#">DEFINITIONS</a>	3
VII.	<a href="#">BACKGROUND</a>	4
VIII.	<a href="#">CODING DISCLAIMER</a>	4
IX.	<a href="#">CODING INFORMATION</a>	5
X.	<a href="#">REFERENCE STATEMENT</a>	15
XI.	<a href="#">REFERENCES</a>	15
XII.	<a href="#">APPROVALS</a>	16

X	New Policy	
	Revising Policy Number	
	Superseding Policy Number	
	Retiring Policy Number	

Johns Hopkins Health Plans (JHHP) provides a full spectrum of health care products and services for Advantage MD, Employer Health Programs, Johns Hopkins Health Plan of Virginia Inc., Priority Partners, and US Family Health Plan. Each line of business possesses its own unique contract, benefits, regulations, and regulators' clinical guidelines that supersede the information outlined in this policy.

- CMS 01.00 [Medical Policy Introduction](#)
- CMS 03.01 [Clinical Trials](#)
- CMS 20.05 [Expanded Access and Compassionate Use](#)

	<b>Johns Hopkins Health Plans</b> <b>Medical Policy Manual</b> <b>Medical Policy</b>	<i>Policy Number</i>	CMS24.12
		<i>Effective Date</i>	02/01/2024
		<i>Approval Date</i>	11/21/2023
	<i>Subject</i> <b>Investigational &amp; Experimental Devices, Treatments, and Health Services</b>	<i>Supersedes Date</i>	02/01/2023
		<i>Page</i>	2 of 16

For Advantage MD, refer to:

- CMS Publication 100-02, Medicare Benefit Policy Manual, Chapter 14- [Medical Devices, Section 10, Coverage of Medical Devices](#)
- [eviCore Guidelines](#) for Laboratory, Radiology, Cardiology, and Musculoskeletal Procedures

For Employer Health Program (EHP), refer to:

- Plan specific Summary Plan Description (SPDs)

For Johns Hopkins Health Plan of Virginia Inc. (JHHPVA), refer to:

- CMS Publication 100-02, Medicare Benefit Policy Manual, Chapter 14- [Medical Devices, Section 10, Coverage of Medical Devices](#)
- [eviCore Guidelines](#) for Laboratory, Radiology, Cardiology, and Musculoskeletal Procedures

For Priority Partners (PPMCO), refer to:

- Code of Maryland Regulations (COMAR) [10.67.06.27](#) Benefits - Limitations
- [eviCore Guidelines](#) for Laboratory, Radiology, Cardiology, and Musculoskeletal Procedures

For Uniformed Services Family Health Plan (USFHP), refer to [TRICARE Policy Manuals](#)

- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 1, Section 2.1 Unproven Drugs, Devices, Medical Treatments and Procedures
- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 8, Section 5.1 Medical Devices

#### IV. SCOPE

This policy addresses coverage exclusions that apply across all lines of business for requests of any device, treatment or health service that is designated as investigational or experimental. This medical policy does not apply to drugs or pharmaceuticals.

#### V. POLICY CRITERIA

- Unless benefits are provided under the member's contract, it is the policy of Johns Hopkins Health Plans (JHHP) to restrict coverage to only the devices, treatments, or health services that are medically necessary.
- JHHP uses high quality scientific evidence and Technology Evaluation Criteria (TEC) to determine medical necessity as defined in [CMS01.00 Medical Policy Introduction](#).
- Any device, treatment, or health service that fails to meet medically necessary criteria for the disease, condition, or stage in treatment for the disease or condition it is requested for, will be considered investigational, experimental, or unproven and be excluded from coverage.
- Unless benefits are provided under the member's contract, the services identified in section IX. CODING INFORMATION have been determined to be investigational and are excluded from coverage. (*The list is not all-inclusive*).
- JHHP recognizes evidence may evolve, and therefore, requests for any device, treatment, or health service that currently is classified as investigational or experimental in this policy may be considered when the following materials, at

	<b>Johns Hopkins Health Plans</b> <b>Medical Policy Manual</b> <b>Medical Policy</b>	<i>Policy Number</i>	CMS24.12
		<i>Effective Date</i>	02/01/2024
		<i>Approval Date</i>	11/21/2023
	<u>Subject</u> <b>Investigational &amp; Experimental Devices, Treatments, and Health Services</b>	<i>Supersedes Date</i>	02/01/2023
		<i>Page</i>	3 of 16

minimum, are submitted. Consideration will be given when materials submitted support the following TEC assessment criteria: (*Refer to Definitions*)

1. One or more high quality:
    - a. Systematic review published in the peer-reviewed medical literature shows clear health benefits equivalent to the standard of care for the disease or condition it is requested for, OR;
    - b. Evidence Synthesis and Guidelines
      - i. Published formal technology assessments, (Hayes, AHRQ), OR;
      - ii. Published clinical guidelines of national professional medical associations, OR;
    - c. Critically Appraised Article Synopses (Articles selected and rated for clinical relevance by physicians; A synopsis of individual research study, generally by a topic expert), OR;
  2. Two or more high quality:
    - a. Published national medical policy organizations and regulatory recommendations;
    - b. Published reports by national expert opinion organizations (e.g., USPSTF);
    - c. Published reports of evidence-based evaluations and clinical support resources (e.g., UpToDate);
    - d. Randomized controlled trials (RCT) and other controlled clinical trials or observation studies published in peer-reviewed medical literature that show clear health benefit equivalent to the standard of care for the disease or condition it is requested for;
    - e. Information from appropriate government regulatory bodies (e.g., Defense Health Agency (DHA), Center for Medicare & Medicaid Services (CMS), Maryland Department of Health (MDH), Food and Drug Administration (FDA)).
- F. For information on coverage of services under clinical trials refer to [CMS03.01 Clinical Trials](#).
- G. For information on coverage of services under expanded access to therapy and services outside of clinical trials, refer to [CMS20.05 Expanded Access and Compassionate Use](#).

## VI. DEFINITIONS

Experimental or Investigational: A device, treatment or health service that is not medically necessary to which any of the following apply:

- Fail to meet the Technology Evaluation Criterion (TEC) outlined in this policy, OR;
- Used for indications not approved by the U.S. Food and Drug Administration (FDA), OR;
- Are generally not accepted as standard medical care in the medical community for the condition, disease, illness, or injury being treated were either,
  - An alternative therapy exists OR;
  - The technology cannot be lawfully marketed without the approval of the U.S. FDA, and approval for marketing has not been given at the time the technology is furnished, OR
  - Lacks appropriate scientific evidence as outlined by the policy criterion E above.

Medically Necessary or Medical Necessity: A device, treatment, or health service that meets the following criteria (COMAR 10.67.01.01):

- Directly related to the diagnostic, preventive, curative, palliative, rehabilitative, or ameliorative treatment of an illness, injury, disability, or health condition, AND;
- Consistent with currently accepted standards of good medical practice, AND;
- The most cost-efficient service that can be provided without sacrificing effectiveness or access to care, AND;

	<b>Johns Hopkins Health Plans</b> <b>Medical Policy Manual</b> <b>Medical Policy</b>	<i>Policy Number</i>	CMS24.12
		<i>Effective Date</i>	02/01/2024
		<i>Approval Date</i>	11/21/2023
	<i>Subject</i> <b>Investigational &amp; Experimental Devices, Treatments, and Health Services</b>	<i>Supersedes Date</i>	02/01/2023
		<i>Page</i>	4 of 16

- Not primarily for the convenience of the consumer, the consumer's family, or the provider.

**Technology Assessment:** The systematic evaluation of the properties, effects, and/or impacts of health technologies and interventions. It covers both the direct, intended consequences of the technologies and interventions and their indirect, unintended consequences (NIH, 2017).

Technology Assessment Criteria (TEC):

- The technology must have final approval from the appropriate government regulatory bodies when indicated (TRICARE, FDA, CMS, MDH), AND;
- There must be sufficient scientific evidence-based studies to permit conclusions concerning the effect of the technology on health outcomes, AND;
- The technology must improve the member's net health outcome, AND;
- The technology must be as beneficial as any established alternatives, AND;
- The improvement must be attainable outside of the investigational settings.

## **VII. BACKGROUND**

Consistent with policy guidelines from the Centers for Medicare and Medicaid (CMS), Code of Maryland Regulations (COMAR), Federal Code of Regulations (CFR), and TRICARE, CMS01.00 Medical Policy Introduction states that it is the policy of JHHP to limit coverage to medically necessary health services and thereby excludes those that are investigational or experimental (I&E). This policy was developed to consolidate known I&E devices, treatments, and health services that are excluded from coverage due to an I&E designation; it is not all-inclusive.

JHHP acknowledges that medical information and scientific evidence are continually evolving. Though the devices, treatments, or health services in section IX. CODING INFORMATION were determined to be investigational or experimental at the time of the policy review, JHHP provides an opportunity for providers to submit any new evidence to support coverage consideration as outlined in Criterion E above. Any evidence submitted must meet JHHP standards of appropriate and acceptable evidence.

## **VIII. CODING DISCLAIMER**


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**Note:** The following CPT/HCPCS codes are included below for informational purposes and may not be all-inclusive. Benefit coverage for health services is determined by the member's specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee of payment. Other policies and coverage determination guidelines may apply.

**Note:** All inpatient admissions require preauthorization.

**Adherence to the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits**

Advantage MD: Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.

	<b>Johns Hopkins Health Plans</b> <b>Medical Policy Manual</b> <b>Medical Policy</b>	<i>Policy Number</i>	CMS24.12
		<i>Effective Date</i>	02/01/2024
		<i>Approval Date</i>	11/21/2023
	<u>Subject</u> <b>Investigational &amp; Experimental Devices, Treatments, and Health Services</b>	<i>Supersedes Date</i>	02/01/2023
		<i>Page</i>	5 of 16

Employer Health Programs (EHP): Specific Summary Plan Descriptions (SPDs) supersedes JHHP Medical Policy. If there are no criteria in the SPD, apply the Medical Policy criteria.

Johns Hopkins Health Plan of Virginia Inc. (JHHPVA): Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.

Priority Partners (PPMCO): Regulatory guidance supersedes JHHP Medical Policy. If there are no criteria in COMAR regulations, or other State guidelines, apply the Medical Policy criteria.

US Family Health Plan (USFHP): Regulatory guidance supersedes JHHP Medical Policy. If there are no TRICARE policies, or other regulatory guidelines, apply the Medical Policy criteria.

## IX. CODING INFORMATION

CPT® CODES ARE FOR INFORMATIONAL PURPOSE ONLY	
CPT® CODES	DESCRIPTION
0014M	Liver disease, analysis of 3 biomarkers (hyaluronic acid [HA], procollagen III amino terminal peptide [PIIINP], tissue inhibitor of metalloproteinase 1 [TIMP-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk of liver fibrosis and liver-related clinical events within 5 years
0015M	Adrenal cortical tumor, biochemical assay of 25 steroid markers, utilizing 24-hour urine specimen and clinical parameters, prognostic algorithm reported as a clinical risk and integrated clinical steroid risk for adrenal cortical carcinoma, adenoma, or other adrenal malignancy
0016M	Oncology (bladder), mRNA, microarray gene expression profiling of 219 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as molecular subtype (luminal, luminal infiltrated, basal, basal claudin-low, neuroendocrine-like)
0017M	Oncology (diffuse large B-cell lymphoma [DLBCL]), mRNA, gene expression profiling by fluorescent probe hybridization of 20 genes, formalin-fixed paraffin-embedded tissue, algorithm reported as cell of origin
0018M	Transplantation medicine (allograft rejection, renal), measurement of donor and third-party-induced CD154+T-cytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as a rejection risk score
0019M	Cardiovascular disease, plasma, analysis of protein biomarkers by aptamer-based microarray and algorithm reported as 4-year likelihood of coronary event in high-risk populations
0152U	Infectious disease (bacteria, fungi, parasites, and DNA viruses), microbial cell-free DNA, plasma, untargeted next-generation sequencing, report for significant positive pathogens
0153U	Oncology (breast), mRNA, gene expression profiling by next-generation sequencing of 101 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a triple negative breast cancer clinical subtype(s) with information on immune cell involvement
0156U	Copy number (eg, intellectual disability, dysmorphology), sequence analysis

	<b>Johns Hopkins Health Plans</b> <b>Medical Policy Manual</b> <b>Medical Policy</b>	<i>Policy Number</i>	CMS24.12
		<i>Effective Date</i>	02/01/2024
		<i>Approval Date</i>	11/21/2023
	<u>Subject</u> <b>Investigational &amp; Experimental Devices, Treatments, and Health Services</b>	<i>Supersedes Date</i>	02/01/2023
		<i>Page</i>	6 of 16

0157U	APC (APC regulator of WNT signaling pathway) (eg, familial adenomatosis polyposis [FAP]) mRNA sequence analysis (List separately in addition to code for primary procedure)
0158U	MLH1 (mutL homolog 1) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)
0159U	MSH2 (mutS homolog 2) (eg, hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)
0160U	MSH6 (mutS homolog 6) (eg, hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)
0161U	PMS2 (PMS1 homolog 2, mismatch repair system component) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure)
0162U	Hereditary colon cancer (Lynch syndrome), targeted mRNA sequence analysis panel (MLH1, MSH2, MSH6, PMS2) (List separately in addition to code for primary procedure)
0163U	Oncology (colorectal) screening, biochemical enzyme-linked immunosorbent assay (ELISA) of 3 plasma or serum proteins (teratocarcinoma derived growth factor-1 [TDGF-1, Cripto-1], carcinoembryonic antigen [CEA], extracellular matrix protein [ECM]), with demographic data (age, gender, CRC-screening compliance) using a proprietary algorithm and reported as likelihood of CRC or advanced adenomas
0164U	Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results
0165U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and probability of peanut allergy
0166U	Liver disease, 10 biochemical assays (α2-macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cholesterol, fasting glucose) and biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflammatory activity, and steatosis with a summary interpretation
0169U	NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants
0170U	Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva, algorithmic analysis, and results reported as predictive probability of ASD diagnosis
0173U	Psychiatry (ie, depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes
0174U	Oncology (solid tumor), mass spectrometric 30 protein targets, formalin-fixed paraffin-embedded tissue, prognostic and predictive algorithm reported as likely, unlikely, or uncertain benefit of 39 chemotherapy and targeted therapeutic oncology agents
0175U	Psychiatry (eg, depression, anxiety), genomic analysis panel, variant analysis of 15 genes
0176U	Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA)
0178U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction

	<b>Johns Hopkins Health Plans</b> <b>Medical Policy Manual</b> <b>Medical Policy</b>	<i>Policy Number</i>	CMS24.12
		<i>Effective Date</i>	02/01/2024
		<i>Approval Date</i>	11/21/2023
	<u>Subject</u> <b>Investigational &amp; Experimental Devices, Treatments, and Health Services</b>	<i>Supersedes Date</i>	02/01/2023
		<i>Page</i>	7 of 16

0203U	Autoimmune (inflammatory bowel disease), mRNA, gene expression profiling by quantitative RT-PCR, 17 genes (15 target and 2 reference genes), whole blood, reported as a continuous risk score and classification of inflammatory bowel disease aggressiveness
0204U	Oncology (thyroid), mRNA, gene expression analysis of 593 genes (including BRAF, RAS, RET, PAX8, and NTRK) for sequence variants and rearrangements, utilizing fine needle aspirate, reported as detected or not detected
0205U	Ophthalmology (age-related macular degeneration), analysis of 3 gene variants (2 CFH gene, 1 ARMS2 gene), using PCR and MALDI-TOF, buccal swab, reported as positive or negative for neovascular age-related macular-degeneration risk associated with zinc supplements
0206U	Neurology (Alzheimer disease); cell aggregation using morphometric imaging and protein kinase C-epsilon (PKCe) concentration in response to amylospheroid treatment by ELISA, cultured skin fibroblasts, each reported as positive or negative for Alzheimer disease
0207U	Neurology (Alzheimer disease); quantitative imaging of phosphorylated ERK1 and ERK2 in response to bradykinin treatment by in situ immunofluorescence, using cultured skin fibroblasts, reported as a probability index for Alzheimer disease (List separately in addition to code for primary procedure)
0209U	Cytogenomic constitutional (genome-wide) analysis, interrogation of genomic regions for copy number, structural changes and areas of homozygosity for chromosomal abnormalities
0212U	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband
0213U	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, each comparator genome (eg, parent, sibling)
0220U	Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score
0227U	Drug assay, presumptive, 30 or more drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, includes sample validation
0228U	Oncology (prostate), multianalyte molecular profile by photometric detection of macromolecules adsorbed on nanosponge array slides with machine learning, utilizing first morning voided urine, algorithm reported as likelihood of prostate cancer
0229U	BCAT1 (Branched chain amino acid transaminase 1) and IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis
0243U	Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia




	<b>Johns Hopkins Health Plans</b> <b>Medical Policy Manual</b> <b>Medical Policy</b>	<i>Policy Number</i>	CMS24.12
		<i>Effective Date</i>	02/01/2024
		<i>Approval Date</i>	11/21/2023
	<u>Subject</u> <b>Investigational &amp; Experimental Devices, Treatments, and Health Services</b>	<i>Supersedes Date</i>	02/01/2023
		<i>Page</i>	8 of 16

0247U	Obstetrics (preterm birth), insulin-like growth factor-binding protein 4 (IBP4), sex hormone-binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal serum, combined with clinical data, reported as predictive-risk stratification for spontaneous preterm birth
0248U	Oncology (brain), spheroid cell culture in a 3D microenvironment, 12 drug panel, tumor-response prediction for each drug
0249U	Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report
0251U	Hepcidin-25, enzyme-linked immunosorbent assay (ELISA), serum or plasma
0252U	Fetal aneuploidy short tandem-repeat comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploidy
0253U	Reproductive medicine (endometrial receptivity analysis), RNA gene expression profile, 238 genes by next-generation sequencing, endometrial tissue, predictive algorithm reported as endometrial window of implantation (eg, pre-receptive, receptive, post-receptive)
0254U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic DNA genomic sequence analysis for aneuploidy, and a mitochondrial DNA score in euploid embryos, results reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploidy, per embryo tested
0255U	Andrology (infertility), sperm-capacitation assessment of ganglioside GM1 distribution patterns, fluorescence microscopy, fresh or frozen specimen, reported as percentage of capacitated sperm and probability of generating a pregnancy score
0258U	Autoimmune (psoriasis), mRNA, next-generation sequencing, gene expression profiling of 50-100 genes, skin-surface collection using adhesive patch, algorithm reported as likelihood of response to psoriasis biologics
0259U	Nephrology (chronic kidney disease), nuclear magnetic resonance spectroscopy measurement of myo-inositol, valine, and creatinine, algorithmically combined with cystatin C (by immunoassay) and demographic data to determine estimated glomerular filtration rate (GFR), serum, quantitative
0260U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping
0261U	Oncology (colorectal cancer), image analysis with artificial intelligence assessment of 4 histologic and immunohistochemical features (CD3 and CD8 within tumor-stroma border and tumor core), tissue, reported as immune response and recurrence-risk score
0262U	Oncology (solid tumor), gene expression profiling by real-time RT-PCR of 7 gene pathways (ER, AR, PI3K, MAPK, HH, TGFB, Notch), formalin-fixed paraffin-embedded (FFPE), algorithm reported as gene pathway activity score



	<b>Johns Hopkins Health Plans</b> <b>Medical Policy Manual</b> <b>Medical Policy</b>	<i>Policy Number</i>	CMS24.12
		<i>Effective Date</i>	02/01/2024
		<i>Approval Date</i>	11/21/2023
	<u>Subject</u> <b>Investigational &amp; Experimental Devices, Treatments, and Health Services</b>	<i>Supersedes Date</i>	02/01/2023
		<i>Page</i>	9 of 16

0263U	Neurology (autism spectrum disorder [ASD]), quantitative measurements of 16 central carbon metabolites (ie, a-ketoglutarate, alanine, lactate, phenylalanine, pyruvate, succinate, carnitine, citrate, fumarate, hypoxanthine, inosine, malate, S-sulfocysteine, taurine, urate, and xanthine), liquid chromatography tandem mass spectrometry (LC-MS/MS), plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD)
0264U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping
0265U	Rare constitutional and other heritable disorders, whole genome and mitochondrial DNA sequence analysis, blood, frozen and formalin-fixed paraffin-embedded (FFPE) tissue, saliva, buccal swabs or cell lines, identification of single nucleotide and copy number variants
0266U	Unexplained constitutional or other heritable disorders or syndromes, tissue-specific gene expression by whole-transcriptome and next-generation sequencing, blood, formalin-fixed paraffin-embedded (FFPE) tissue or fresh frozen tissue, reported as presence or absence of splicing or expression changes
0267U	Rare constitutional and other heritable disorders, identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping and whole genome sequencing
0285U	Oncology, response to radiation, cell-free DNA, quantitative branched chain DNA amplification, plasma, reported as a radiation toxicity score
0288U	Oncology (lung), mRNA, quantitative PCR analysis of 11 genes (BAG1, BRCA1, CDC6, CDK2AP1, ERBB3, FUT3, IL11, LCK, RND3, SH3BGR, WNT3A) and 3 reference genes (ESD, TBP, YAP1), formalin-fixed paraffin-embedded (FFPE) tumor tissue, algorithmic interpretation reported as a recurrence risk score
0289U	Neurology (Alzheimer disease), mRNA, gene expression profiling by RNA sequencing of 24 genes, whole blood, algorithm reported as predictive risk score
0290U	Pain management, mRNA, gene expression profiling by RNA sequencing of 36 genes, whole blood, algorithm reported as predictive risk score
0291U	Psychiatry (mood disorders), mRNA, gene expression profiling by RNA sequencing of 144 genes, whole blood, algorithm reported as predictive risk score
0292U	Psychiatry (stress disorders), mRNA, gene expression profiling by RNA sequencing of 72 genes, whole blood, algorithm reported as predictive risk score
0293U	Psychiatry (suicidal ideation), mRNA, gene expression profiling by RNA sequencing of 54 genes, whole blood, algorithm reported as predictive risk score
0294U	Longevity and mortality risk, mRNA, gene expression profiling by RNA sequencing of 18 genes, whole blood, algorithm reported as predictive risk score
0295U	Oncology (breast ductal carcinoma in situ), protein expression profiling by immunohistochemistry of 7 proteins (COX2, FOXA1, HER2, Ki-67, p16, PR, SIAH2), with 4 clinicopathologic factors (size, age, margin status, palpability), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a recurrence risk score

	<b>Johns Hopkins Health Plans</b> <b>Medical Policy Manual</b> <b>Medical Policy</b>	<i>Policy Number</i>	CMS24.12
		<i>Effective Date</i>	02/01/2024
		<i>Approval Date</i>	11/21/2023
	<u>Subject</u> <b>Investigational &amp; Experimental Devices, Treatments, and Health Services</b>	<i>Supersedes Date</i>	02/01/2023
		<i>Page</i>	10 of 16

0296U	Oncology (oral and/or oropharyngeal cancer), gene expression profiling by RNA sequencing of at least 20 molecular features (eg, human and/or microbial mRNA), saliva, algorithm reported as positive or negative for signature associated with malignancy
0297U	Oncology (pan tumor), whole genome sequencing of paired malignant and normal DNA specimens, fresh or formalin-fixed paraffin-embedded (FFPE) tissue, blood or bone marrow, comparative sequence analyses and variant identification
0298U	Oncology (pan tumor), whole transcriptome sequencing of paired malignant and normal RNA specimens, fresh or formalin-fixed paraffin-embedded (FFPE) tissue, blood or bone marrow, comparative sequence analyses and expression level and chimeric transcript identification
0299U	Oncology (pan tumor), whole genome optical genome mapping of paired malignant and normal DNA specimens, fresh frozen tissue, blood, or bone marrow, comparative structural variant identification
0300U	Oncology (pan tumor), whole genome sequencing and optical genome mapping of paired malignant and normal DNA specimens, fresh tissue, blood, or bone marrow, comparative sequence analyses and variant identification
0301U	Infectious agent detection by nucleic acid (DNA or RNA), Bartonella henselae and Bartonella quintana, droplet digital PCR (ddPCR);
0302U	Infectious agent detection by nucleic acid (DNA or RNA), Bartonella henselae and Bartonella quintana, droplet digital PCR (ddPCR); following liquid enhancement
0303U	Hematology, red blood cell (RBC) adhesion to endothelial/subendothelial adhesion molecules, functional assessment, whole blood, with algorithmic analysis and result reported as an RBC adhesion index; hypoxic
0304U	Hematology, red blood cell (RBC) adhesion to endothelial/subendothelial adhesion molecules, functional assessment, whole blood, with algorithmic analysis and result reported as an RBC adhesion index; normoxic
0305U	Hematology, red blood cell (RBC) functionality and deformity as a function of shear stress, whole blood, reported as a maximum elongation index
0306U	Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis, cell-free DNA, initial (baseline) assessment to determine a patient-specific panel for future comparisons to evaluate for MRD
0307U	Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis of a patient-specific panel, cell-free DNA, subsequent assessment with comparison to previously analyzed patient specimens to evaluate for MRD
0308U	Cardiology (coronary artery disease [CAD]), analysis of 3 proteins (high sensitivity [hs] troponin, adiponectin, and kidney injury molecule-1 [KIM-1]), plasma, algorithm reported as a risk score for obstructive CAD
0309U	Cardiology (cardiovascular disease), analysis of 4 proteins (NT-proBNP, osteopontin, tissue inhibitor of metalloproteinase-1 [TIMP-1], and kidney injury molecule-1 [KIM-1]), plasma, algorithm reported as a risk score for major adverse cardiac event
0310U	Pediatrics (vasculitis, Kawasaki disease [KD]), analysis of 3 biomarkers (NT-proBNP, C-reactive protein, and T-uptake), plasma, algorithm reported as a risk score for KD

	Johns Hopkins Health Plans <b>Medical Policy Manual</b> <b>Medical Policy</b>	<i>Policy Number</i>	CMS24.12
		<i>Effective Date</i>	02/01/2024
		<i>Approval Date</i>	11/21/2023
	<u>Subject</u> <b>Investigational &amp; Experimental Devices, Treatments, and Health Services</b>	<i>Supersedes Date</i>	02/01/2023
		<i>Page</i>	11 of 16

0312U	Autoimmune diseases (eg, 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
0314U	Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 35 genes (32 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical result (ie, benign, intermediate, malignant)
0315U	Oncology (cutaneous squamous cell carcinoma), mRNA gene expression profiling by RT-PCR of 40 genes (34 content and 6 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical risk result (ie, Class 1, Class 2A, Class 2B)
0316U	Borrelia burgdorferi (Lyme disease), OspA protein evaluation, urine
0317U	Oncology (lung cancer), four-probe FISH (3q29, 3p22.1, 10q22.3, 10cen) assay, whole blood, predictive algorithm-generated evaluation reported as decreased or increased risk for lung cancer
0318U	Pediatrics (congenital epigenetic disorders), whole genome methylation analysis by microarray for 50 or more genes, blood
0319U	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using pretransplant peripheral blood, algorithm reported as a risk score for early acute rejection
0320U	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using posttransplant peripheral blood, algorithm reported as a risk score for acute cellular rejection
0321U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms and identification of 16 associated antibiotic-resistance genes, multiplex amplified probe technique
0322U	Neurology (autism spectrum disorder [ASD]), quantitative measurements of 14 acyl carnitines and microbiome-derived metabolites, liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma, results reported as negative or positive for risk of metabolic subtypes associated with ASD
0323U	Infectious agent detection by nucleic acid (DNA and RNA), central nervous system pathogen, metagenomic next-generation sequencing, cerebrospinal fluid (CSF), identification of pathogenic bacteria, viruses, parasites, or fungi
0328U	Drug assay, definitive, 120 or more drugs and metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS), includes specimen validity and algorithmic analysis describing drug or metabolite and presence or absence of risks for a significant patient-adverse event, per date of service
0329U	Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations
0330U	Infectious agent detection by nucleic acid (DNA or RNA), vaginal pathogen panel, identification of 27 organisms, amplified probe technique, vaginal swab

	<b>Johns Hopkins Health Plans</b> <b>Medical Policy Manual</b> <b>Medical Policy</b>	<i>Policy Number</i>	CMS24.12
		<i>Effective Date</i>	02/01/2024
		<i>Approval Date</i>	11/21/2023
	<u>Subject</u> <b>Investigational &amp; Experimental Devices, Treatments, and Health Services</b>	<i>Supersedes Date</i>	02/01/2023
		<i>Page</i>	12 of 16

0331U	Oncology (hematolymphoid neoplasia), optical genome mapping for copy number alterations and gene rearrangements utilizing DNA from blood or bone marrow, report of clinically significant alterations
0332U	Oncology (pan-tumor), genetic profiling of 8 DNA-regulatory (epigenetic) markers by quantitative polymerase chain reaction (qPCR), whole blood, reported as a high or low probability of responding to immune checkpoint-inhibitor therapy
0333U	Oncology (liver), surveillance for hepatocellular carcinoma (HCC) in high-risk patients, analysis of methylation patterns on circulating cell-free DNA (cfDNA) plus measurement of serum of AFP/AFP-L3 and oncoprotein des-gamma-carboxy-prothrombin (DCP), algorithm reported as normal or abnormal result
0335U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions, fetal sample, identification and categorization of genetic variants
0336U	Rare diseases (constitutional/heritable disorders), whole genome sequence analysis, including small sequence changes, copy number variants, deletions, duplications, mobile element insertions, uniparental disomy (UPD), inversions, aneuploidy, mitochondrial genome sequence analysis with heteroplasmy and large deletions, short tandem repeat (STR) gene expansions, blood or saliva, identification and categorization of genetic variants, each comparator genome (eg, parent)
0337U	Oncology (plasma cell disorders and myeloma), circulating plasma cell immunologic selection, identification, morphological characterization, and enumeration of plasma cells based on differential CD138, CD38, CD19, and CD45 protein biomarker expression, peripheral blood
0338U	Oncology (solid tumor), circulating tumor cell selection, identification, morphological characterization, detection and enumeration based on differential EpCAM, cytokeratins 8, 18, and 19, and CD45 protein biomarkers, and quantification of HER2 protein biomarker-expressing cells, peripheral blood
0340U	Oncology (pan-cancer), analysis of minimal residual disease (MRD) from plasma, with assays personalized to each patient based on prior next-generation sequencing of the patient's tumor and germline DNA, reported as absence or presence of MRD, with disease-burden correlation, if appropriate
0341U	Fetal aneuploidy DNA sequencing comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploid
0342U	Oncology (pancreatic cancer), multiplex immunoassay of C5, C4, cystatin C, factor B, osteoprotegerin (OPG), gelsolin, IGFBP3, CA125 and multiplex electrochemiluminescent immunoassay (ECLIA) for CA19-9, serum, diagnostic algorithm reported qualitatively as positive, negative, or borderline
0343U	Oncology (prostate), exosome-based analysis of 442 small noncoding RNAs (sncRNAs) by quantitative reverse transcription polymerase chain reaction (RT-qPCR), urine, reported as molecular evidence of no-, low-, intermediate- or high-risk of prostate cancer
0344U	Hepatology (nonalcoholic fatty liver disease [NAFLD]), semiquantitative evaluation of 28 lipid markers by liquid chromatography with tandem mass spectrometry (LC-MS/MS), serum, reported as at-risk for nonalcoholic steatohepatitis (NASH) or not NASH

	<b>Johns Hopkins Health Plans</b> <b>Medical Policy Manual</b> <b>Medical Policy</b>	<i>Policy Number</i>	CMS24.12
		<i>Effective Date</i>	02/01/2024
		<i>Approval Date</i>	11/21/2023
	<u>Subject</u> <b>Investigational &amp; Experimental Devices, Treatments, and Health Services</b>	<i>Supersedes Date</i>	02/01/2023
		<i>Page</i>	13 of 16

0355U	APOL1 (apolipoprotein L1) (eg, chronic kidney disease), risk variants (G1, G2)
0356U	Oncology (oropharyngeal or anal), evaluation of 17 DNA biomarkers using droplet digital PCR (ddPCR), cell-free DNA, algorithm reported as a prognostic risk score for cancer recurrence
0358U	Neurology (mild cognitive impairment), analysis of $\beta$ -amyloid 1-42 and 1-40, chemiluminescence enzyme immunoassay, cerebral spinal fluid, reported as positive, likely positive, or negative
0359U	Oncology (prostate cancer), analysis of all prostate-specific antigen (PSA) structural isoforms by phase separation and immunoassay, plasma, algorithm reports risk of cancer
0360U	Oncology (lung), enzyme-linked immunosorbent assay (ELISA) of 7 autoantibodies (p53, NY-ESO-1, CAGE, GBU4-5, SOX2, MAGE A4, and HuD), plasma, algorithm reported as a categorical result for risk of malignancy
0361U	Neurofilament light chain, digital immunoassay, plasma, quantitative
0362U	Oncology (papillary thyroid cancer), gene-expression profiling via targeted hybrid capture-enrichment RNA sequencing of 82 content genes and 10 housekeeping genes, fine needle aspirate or formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as one of three molecular subtypes
0365U	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
0366U	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
0367U	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
0368U	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 cancer
0375U	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
0376U	Oncology (prostate cancer), image analysis of at least 128 histologic features and clinical factors, prognostic algorithm determining the risk of distant metastases, and prostate cancer-specific mortality, includes predictive algorithm to androgen deprivation-therapy response, if appropriate
0384U	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



	<b>Johns Hopkins Health Plans</b> <b>Medical Policy Manual</b> <b>Medical Policy</b>	<i>Policy Number</i>	CMS24.12
		<i>Effective Date</i>	02/01/2024
		<i>Approval Date</i>	11/21/2023
	<u>Subject</u> <b>Investigational &amp; Experimental Devices, Treatments, and Health Services</b>	<i>Supersedes Date</i>	02/01/2023
		<i>Page</i>	14 of 16

0385U	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
0387U	Oncology (melanoma), autophagy and beclin 1 regulator 1 (AMBRA1) and loricrin (AMLo) by immunohistochemistry, formalin-fixed paraffin-embedded (FFPE) tissue, report for risk of progression
0389U	Pediatric febrile illness (Kawasaki disease [KD]), interferon alpha-inducible protein 27 (IFI27) and mast cell-expressed membrane protein 1 (MCEMP1), RNA, using quantitative reverse transcription polymerase chain reaction (RT-qPCR), blood, reported as a risk score for KD
0390U	Obstetrics (preeclampsia), kinase insert domain receptor (KDR), Endoglin (ENG), and retinol-binding protein 4 (RBP4), by immunoassay, serum, algorithm reported as a risk score
0391U	Oncology (solid tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded (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
0395U	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
0396U	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
0398U	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
0399U	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
0401U	Cardiology (coronary heart disease [CHD]), 9 genes (12 variants), targeted variant genotyping, blood, saliva, or buccal swab, algorithm reported as a genetic risk score for a coronary event
0403U	Oncology (prostate), mRNA, gene expression profiling of 18 genes, first-catch post-digital rectal examination urine (or processed first-catch urine), algorithm reported as percentage of likelihood of detecting clinically significant prostate cancer
0404U	Oncology (breast), semiquantitative measurement of thymidine kinase activity by immunoassay, serum, results reported as risk of disease progression
0405U	Oncology (pancreatic), 59 methylation haplotype block markers, next-generation sequencing, plasma, reported as cancer signal detected or not detected
0406U	Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4-carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer



	<b>Johns Hopkins Health Plans</b> <b>Medical Policy Manual</b> <b>Medical Policy</b>	<i>Policy Number</i>	CMS24.12
		<i>Effective Date</i>	02/01/2024
		<i>Approval Date</i>	11/21/2023
	<i>Subject</i> <b>Investigational &amp; Experimental Devices, Treatments, and Health Services</b>	<i>Supersedes Date</i>	02/01/2023
		<i>Page</i>	15 of 16

0407U	Nephrology (diabetic chronic kidney disease [CKD]), multiplex electrochemiluminescent immunoassay (ECLIA) of soluble tumor necrosis factor receptor 1 (sTNFR1), soluble tumor necrosis receptor 2 (sTNFR2), and kidney injury molecule 1 (KIM-1) combined with clinical data, plasma, algorithm reported as risk for progressive decline in kidney function
0410U	Oncology (pancreatic), DNA, whole genome sequencing with 5-hydroxymethylcytosine enrichment, whole blood or plasma, algorithm reported as cancer detected or not detected
0412U	Beta amyloid, AB42/40 ratio, immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS) and qualitative ApoE isoform-specific proteotyping, plasma combined with age, algorithm reported as presence or absence of brain amyloid pathology
0413U	Oncology (hematolymphoid neoplasm), optical genome mapping for copy number alterations, aneuploidy, and balanced/complex structural rearrangements, DNA from blood or bone marrow, report of clinically significant alterations
0414U	Oncology (lung), augmentative algorithmic analysis of digitized whole slide imaging for 8 genes (ALK, BRAF, EGFR, ERBB2, MET, NTRK1-3, RET, ROS1), and KRAS G12C and PD-L1, if performed, formalin-fixed paraffin-embedded (FFPE) tissue, reported as positive or negative for each biomarker
0418U	Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score
81529	Oncology (cutaneous melanoma), mRNA, gene expression profiling by real-time RT-PCR of 31 genes (28 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk, including likelihood of sentinel lymph node metastasis
81554	Pulmonary disease (idiopathic pulmonary fibrosis [IPF]), mRNA, gene expression analysis of 190 genes, utilizing transbronchial biopsies, diagnostic algorithm reported as categorical result (eg, positive or negative for high probability of usual interstitial pneumonia [UIP])

## **X. REFERENCE STATEMENT**

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins Health Plans (JHHP) Medical Policy Team during the development and implementation of this medical policy. The Medical Policy Team will continue to monitor and review any newly published clinical evidence and revise the policy and adjust the references below accordingly if deemed necessary.

## **XI. REFERENCES**

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	<b>Johns Hopkins Health Plans</b> <b>Medical Policy Manual</b> <b>Medical Policy</b>	<i>Policy Number</i>	CMS24.12
		<i>Effective Date</i>	02/01/2024
		<i>Approval Date</i>	11/21/2023
	<i>Subject</i> <b>Investigational &amp; Experimental Devices, Treatments, and Health Services</b>	<i>Supersedes Date</i>	02/01/2023
		<i>Page</i>	16 of 16

JHHP Medical Policy [CMS01.00 Medical Policy Introduction](#)

JHHP Medical Policy [CMS03.01 Clinical Trials](#)

JHHP Medical Policy [CMS20.05 Expanded Access and Compassionate Use](#)

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## **XII. APPROVALS**

Historical Effective Dates: 02/01/2023, 02/01/2024