


MEDICAL POLICY	Chemosensitivity and Chemoresistance Assays (CSRAs) (Medicare Only)
Effective Date: 7/1/2022  7/1/2022	Medical Policy Number: 329 Medical Policy Committee Approved Date: 5/2022
Medical Officer Date	

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

Medicare Only

MEDICARE POLICY CRITERIA	
<p>The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.</p>	
Service	Medicare Guidelines
<i>Chemotherapy and Drug Sensitivity Assays for Stem Cell Tumors (e.g., the Fluorescent Cytoprint Assay, ChemID [0564T])</i>	National Coverage Determination (NCD): Human Tumor Stem Cell Drug Sensitivity Assays (190.7)
<i>Onco4D™, by Animated Dynamics Inc. (0083U; Indiana)</i>	LCD: Special Histochemical Stains and Immunohistochemical Stains (L36805) (This LCD reads, “Chemosensitivity profile tumor panels, regardless of whether it is performed by IHC or chromogenic in-situ hybridization (CISH), is not reasonable and necessary for the reasons cited above and is not a Medicare covered service.”)
<i>3D Predict™ tests (KIYATEC® Inc.; South Carolina)</i>	Local Coverage Determination (LCD): In Vitro Chemosensitivity & Chemoresistance Assays (L34554) (See “Policy Guidelines” about investigational services and medical necessity for Medicare)

MEDICAL POLICY	Chemosensitivity and Chemoresistance Assays (CRSAs) (Medicare Only)
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<ul style="list-style-type: none"> • 3D Predict Glioma test (0248U) • 3D Predict™ Ovarian Doublet Panel (0324U) • 3D Predict™ Ovarian PARP Panel (0325U) 	<p>Testing performed in AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY: Local Coverage Determinations (LCD): In Vitro Chemosensitivity & Chemoresistance Assays (L37630) (See “Policy Guidelines” about investigational services and medical necessity for Medicare)</p> <p>NOTE: The above LCD is the primary source of criteria/guidance for CRSAs. However, additional information regarding some chemosensitivity / chemoresistance assays can also be found in the LCD for <i>Lab: Special Histochemical Stains and Immunohistochemical Stains</i> (L36353), specifically in the section for “IHC for Chemosensitivity and Resistance Tumor Profiling.”</p>
<p><i>General Chemosensitivity and Chemoresistance Assay (CSRA) Testing</i></p>	<p><i>In the absence of a Medicare coverage policy or guidance (e.g., manual, national coverage determination [NCD], local coverage determination [LCD] article [LCA], etc.), Medicare guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an objective, evidence-based process, based on authoritative evidence. (Medicare Managed Care Manual, Ch. 4, §90.5) Therefore, the commercial medical policy, Chemoresistance and Chemosensitivity Assays (All Lines of Business Except Medicare), applies to the following services:</i></p> <ul style="list-style-type: none"> • ChemoFX®, performed by Helomics [previously Precision Therapeutics, Inc.], in Pittsburgh, PA

BILLING GUIDELINES

General

See associated local coverage articles (LCAs) for related billing and coding guidance:

- LCA: Billing and Coding: In Vitro Chemosensitivity & Chemoresistance Assays ([A56073](#))
- LCA: Billing and Coding: Lab: Special Histochemical Stains and Immunohistochemical Stains ([A57614](#))

MEDICAL POLICY	Chemosensitivity and Chemoresistance Assays (CRSAs) (Medicare Only)
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CPT/HCPCS CODES

Medicare Only	
Not Covered	
0083U	Oncology, response to chemotherapy drugs using motility contrast tomography, fresh or frozen tissue, reported as likelihood of sensitivity or resistance to drugs or drug combinations <i>(Use for Onco4D™, by Animated Dynamics Inc.)</i>
0248U	Oncology (brain), spheroid cell culture in a 3D microenvironment, 12 drug panel, tumor-response prediction for each drug <i>(Use for the 3D Predict Glioma test, by KIYATEC® Inc.)</i>
0564T	Oncology, chemotherapeutic drug cytotoxicity assay of cancer stem cells (CSCs), from cultured CSCs and primary tumor cells, categorical drug response reported based on percent of cytotoxicity observed, a minimum of 14 drugs or drug combinations <i>(Use for ChemID)</i>
0324U	Oncology (ovarian), spheroid cell culture, 4-drug panel (carboplatin, doxorubicin, gemcitabine, paclitaxel), tumor chemotherapy response prediction for each drug <i>(Use for the 3D Predict™ Ovarian Doublet Panel test, by KIYATEC® Inc.)</i>
0325U	Oncology (ovarian), spheroid cell culture, poly (ADP-ribose) polymerase (PARP) inhibitors (niraparib, olaparib, rucaparib, velparib), tumor response prediction for each drug <i>(Use for the 3D Predict™ Ovarian PARP Panel test, by KIYATEC® Inc.)</i>
81535	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; first single drug or drug combination
81536	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; each additional single drug or drug combination (List separately in addition to code for primary procedure)
Unlisted Codes	
All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be denied as not covered .	
86849	Tissue Typing Immunological Procedures
87999	Unlisted microbiology procedure
88299	Unlisted cytogenetic study
89240	Unlisted miscellaneous pathology test

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to

MEDICAL POLICY	Chemosensitivity and Chemoresistance Assays (CRSAs) (Medicare Only)
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determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.