Medicare Medical Policy

Chemosensitivity and Chemoresistance Assays (CSRAs)

MEDICARE MEDICAL POLICY NUMBER: 329

Effective Date: 8/1/2023

Last Review Date: 5/2023

Next Annual Review: 5/2024

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. 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.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

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”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
*Chemotherapy and Drug **Sensitivity** Assays for **Stem Cell Tumors** (e.g., the Fluorescent Cytoprint Assay, ChemoID [0564T])*	National Coverage Determination (NCD): Human Tumor Stem Cell Drug Sensitivity Assays (190.7)
Onco4D™, by Animated Dynamics Inc. (0083U; Indiana)	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."*
General Chemosensitivity and Chemoresistance Assay (CSRA) Testing *Includes 3D Predict™ tests (KIYATEC® Inc.; South Carolina)* • *3D Predict Glioma test (0248U)* • *3D Predict™ Ovarian Doublet Panel* • *3D Predict™ Ovarian PARP Panel*	• **Testing performed in AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY:** Local Coverage Determinations (LCD): In Vitro Chemosensitivity & Chemoresistance Assays (L37630) • **Testing performed in CA or NV:** Local Coverage Determinations (LCD): In Vitro Chemosensitivity & Chemoresistance Assays (L37628) • **Testing performed in AL, GA, TN, VA, WV, SC, NC:** Local Coverage Determination (LCD): In Vitro Chemosensitivity & Chemoresistance Assays (L34554) **NOTE:** See "Policy Guidelines" about investigational services and medical necessity for Medicare. **NOTE:** The above LCD is the primary source of criteria/guidance for CSRAs. However, additional information regarding some chemosensitivity / chemoresistance assays can also be found in the LCD for *Lab: Special Histochemical Stains and Immunohistochemical Stains* (L36353), specifically in the section for "IHC for Chemosensitivity and Resistance Tumor Profiling."

ChemoFX®, performed by Helomics [previously Precision Therapeutics, Inc.], in Pittsburgh, PA	Company medical policy for Chemoresistance and Chemosensitivity Assays I. This service is considered **not medically necessary** for Medicare based on the Company medical policy. *See Policy Guidelines below.*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

MEDICARE AND MEDICAL NECESSITY

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*.

Services Considered "Investigational" Within an LCD

Services which lack scientific evidence regarding safety and efficacy because they are investigational are "not medically reasonable or necessary" for Medicare Plan members. *(Medicare Claims Processing Manual, Ch. 23, §30 A)*

Services Without a Specific NCD or LCD

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.) which addresses the medical necessity of a given medical service, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. *(Medicare Managed Care Manual, Ch. 4, §90.5)*

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

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)

CODES*		
CPT	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 *(Use for Onco4D™, by Animated Dynamics Inc.)*
	0248U	Oncology (brain), spheroid cell culture in a 3D microenvironment, 12 drug panel, tumor-response prediction for each drug *(Use for the 3D Predict Glioma test, by KIYATEC® Inc.)*
	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 *(Use for ChemoID)*
	~~0324U~~	**TERMED 3/31/2023** ~~Oncology (ovarian), spheroid cell culture, 4-drug panel (carboplatin, doxorubicin, gemcitabine, paclitaxel), tumor chemotherapy response prediction for each drug *(Use for the 3D Predict™ Ovarian Doublet Panel test, by KIYATEC® Inc.)*~~
	~~0325U~~	**TERMED 3/31/2023** ~~Oncology (ovarian), spheroid cell culture, poly (ADP-ribose) polymerase (PARP) inhibitors (niraparib, olaparib, rucaparib, velparib), tumor response prediction for each drug *(Use for the 3D Predict™ Ovarian PARP Panel test, by KIYATEC® Inc.)*~~
	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)
	86849	Tissue Typing Immunological Procedures
	87999	Unlisted microbiology procedure
	88299	Unlisted cytogenetic study

	89240	Unlisted miscellaneous pathology test
HCPCS	None	

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

None

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
7/2022	New Medicare Advantage medical policy (converted to new format 2/2023)
4/2023	Q2 2023 code update (termed codes 0324U and 0325U)
8/2023	Annual review, no change to criteria, but language revision due to Company policy change from "investigational" to "not medically necessary"