I. POLICY/CRITERIA

A. The specific use of ChemoFx® is currently only approved for ovarian, fallopian tube and primary peritoneal cancers when intended for guidance in selection of chemotherapeutic agents for either primary or recurrent cancer.

B. All other Chemosensitivity assays are considered experimental and investigational.

Refer to the Multi-Marker Tumor Panels medical policy 91609 for information regarding multi-marker testing.

II. MEDICAL NECESSITY REVIEW

☐ Required ☐ Not Required ☐ Not Applicable

☐ All tests performed at non-participating laboratories will require prior authorization for all products.

III. APPLICATION TO PRODUCTS

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

❖ HMO/EPO: This policy applies to insured HMO/EPO plans.
❖ POS: This policy applies to insured POS plans.
❖ PPO: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
❖ ASO: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
❖ INDIVIDUAL: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
❖ MEDICARE: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
❖ MEDICAID/HEALTHY MICHIGAN PLAN: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met.
IV. DESCRIPTION

Chemosensitivity assays are designed to predict tumor response to various chemotherapies. These assays have been proposed for use by oncologists to select chemotherapy regimens for individual patients. A variety of assays have been developed that differ in their processing and in the technique used to measure sensitivity or resistance. All involve the same four basic steps: 1) isolation of cells, 2) incubation of cells with drugs, 3) assessment of cell survival, and 4) interpretation of the result. A variety of techniques have been evaluated to assess cell survival, including the DISC (differential staining cytotoxicity) assay, the thymidine incorporation assay, fluorescence (cytoprint) assays, and the MTT (methylthiazolyl-diphenly-tetrazolium bromide) assay.

Results are reported as either drug sensitive, drug resistant, or intermediate. Drugs identified as drug sensitive are thought to be potentially effective in chemotherapy, while drugs identified as resistant are thought to be potentially ineffective chemotherapies.

V. CODING INFORMATION

ICD-10 Codes that may support medical necessity:
- C45.1 Mesothelioma of peritoneum
- C48.0 Malignant neoplasm of retroperitoneum
- C48.1 Malignant neoplasm of specified parts of peritoneum
- C48.2 Malignant neoplasm of peritoneum, unspecified
- C48.8 Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
- C56.1 Malignant neoplasm of right ovary
- C56.2 Malignant neoplasm of left ovary
- C56.9 Malignant neoplasm of unspecified ovary
- C57.00 Malignant neoplasm of unspecified fallopian tube
- C57.01 Malignant neoplasm of right fallopian tube
- C57.02 Malignant neoplasm of left fallopian tube

CPT/HCPCS Codes:
- 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 each additional single drug or drug combination (List separately in addition to code for primary procedure)

See also policies:
- 91540 Genetics: Counseling, Testing, Screening
VI. REFERENCES


Hayes Technology Assessment: ChemoFX® Assay (Precision Therapeutics Inc.) for Prediction of Response to Chemotherapy February 26, 2009


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Priority Health’s medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan’s ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

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