

UPMC Health Plan POLICY AND PROCEDURE MANUAL

POLICY NUMBER: PAY.058
REVISION DATE: 09/09
ANNUAL APPROVAL DATE: 11/09
PAGE NUMBER: 1 of 5

SUBJECT: ChemoFx[®] Assay (Medicare Only)
INDEX TITLE: Medical Management
ORIGINAL DATE: June 2008

This policy applies to the following lines of business: (Check those that apply.)

Commercial:					
HMO ()		POS ()		PPO ()	
Fully Insured ()		Self-funded/ASO ()		HSA ()	
Medicare Select ()		Medicare Supplement ()			
DPW-MA:					
Health Choices ()			Voluntary ()		All ()
CMS-MA:					
OH ()		WV ()		PA ()	All (X)
HMO (X)	PPO (X)	Specialty Needs Plan (X)		Part D ()	PFFS (X)
PID-CHIP:					
Free ()		Sub ()		Full ()	All ()
APPLICABLE TO:					
Community Care ()		Work Partners ()			

I. POLICY

It is the policy of UPMC Health Plan to recognize coverage for services mandated through Medicare regulations. Based on the review of the clinical trials performed and the varied data outcomes, it remains unclear whether there is sufficient evidence that the ChemoFx[®] Assay affects clinical decision making or improves health outcomes. UPMC Health Plan considers this procedure to be experimental/ investigational and, therefore, **covered only for Medicare members as outlined in this policy.**

Coverage for Medicare members will be considered for the specific indications detailed in this policy when it is medically necessary and covered under the member's specific benefit plan.

II. DEFINITION

N/A

III. PURPOSE

The purpose of this policy is to define the appropriate indications for coverage of the ChemoFx[®] Assay.

IV. SCOPE

This policy applies to various UPMC Health Plan departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to: Medical Management, Benefit Configuration, and Claims departments.

V. PROCEDURE

A. Medical Description/Background

ChemoFx[®] Assay is a cell-based laboratory test that determines the sensitivity or resistance of cancer cells to specific chemotherapeutic drugs. This assay is intended to provide oncologists with information that assists in the selection of chemotherapy for each individual patient. The chemosensitivity portion of the assay indicates which drugs might be more sensitive while the chemoresistance portion of the assay indicates which drugs are unlikely to affect the tumor. The desired outcome from using the assay would be a reduction in treatment-associated patient adverse events, tumor response failures, and that overall patient survival will be improved. Precision Therapeutics, Inc., which manufactures this test locally documents that testing is indicated in over fifteen types of solid tumors, with ovarian and breast tumors being primarily tested. This assay consists of four basic steps:

- Isolation of the cell
- Incubation of the cells with drugs
- Assessment of cell survival
- Interpretation of the test results

The American Society of Clinical Oncology (ASCO) Working Group found insufficient evidence to support the use of any chemotherapy sensitivity and resistance assays in oncological practice. They specifically found limitations in the literature that included small sample sizes and a lack of prospective studies. They also felt that preparation of the assay might involve complex laboratory work which could limit a broad application of the technology to routine clinical practice. Because the in vitro (outside the body) assay has potential importance, participation in clinical trials evaluating these technologies does remain a priority.

The general consensus in the medical community at this time is there is insufficient evidence that this test influences patient management decisions and improves health outcomes. Results from chemosensitivity assays have demonstrated that the results obtained in vitro (outside the body) have failed to respond as predicted when chemolytic agents are administered in vivo (within the body). Well-designed prospective, randomized controlled clinical trials are needed to further determine the clinical role of this assay-directed therapy and its impact on tumor response.

In 2006, Medicare officially recognized cancer chemosensitivity tests as a special test category. Highmark Medicare Services as the local contractor for Medicare provides coverage for in vitro chemosensitivity and chemoresistance assays performed by Precision Therapeutics, Inc.

B. Indications

This test is applicable to all of the following solid tumors:

- Ovarian **and**
- Other gynecological malignancies

C. Limitations

- **Coverage is limited to:**
 1. Only one unit of service for the human tumor culture and preparation service per tumor assay **and**
 2. Each cancer chemotherapeutic agent or combination of agents assayed can only be billed for a total of 8 units of service for in vitro chemoresistance and sensitivity
 3. Selection of chemotherapy agents used in the assay must be based on FDA approved drug use based on the patient's specific tumor type.
- **This test will only be reimbursable for Precision Therapeutics, Inc., for Medicare members**
- **The Extreme Drug Resistance (EDR) Assay by Oncotech is considered experimental/investigational and, therefore, not a covered benefit**

D. Variations

N/A

E. Audit

Quality Audit may monitor policy compliance or billing accuracy at the request of the UPMC Health Plan's Technology Assessment Committee or the Benefits Reimbursement Committee.

F. Records Retention

Records Retention for UPMC Health Plan documents, regardless of medium are provided within the UPMC Health System Policy and as indicated in the UPMC Insurance Services Division Policy and Procedure.

H. References

1. Highmark Medicare Services Provider Bulletin, *Oncologic In Vitro Chemoresponse Assays*, June 13, 2007
2. Highmark Medicare Services, Billing & Coding Article: *In Vitro Chemoresponse Assays*, 08/04/2004
3. Centers for Medicare & Medicaid Services (CMS), Coverage Article for *In Vitro Chemoresponse Assays* (A22495), 08/04/2004
4. Cigna HealthCare, Coverage Position 0203, *Tumor In Vitro Chemosensitivity and Chemoresistance Assays*, 11/15/2007
5. Precision Therapeutics, ChemoFx[®] Assay, www.precisiontherapeutics.com
6. PubMed – Methods Mol Biol. 2008;414:57-78, Brower SL, Fensterer JE, Bush, JE, *The ChemoFx assay: an ex vivo chemosensitivity and resistance assay for predicting patient response to cancer chemotherapy*
7. AmeriHealth, Coding Guidelines and Policy Update, Volume 2, Issue 4, Winter 2005, *In Vitro Chemosensitivity and Chemoresistance Assays* (06.02.14b)
8. Highmark Medicare Advantage Medical Policy L-58, *Oncologic In Vitro Chemoresponse Assays*, Issued Date 03/17/08

Disclaimer:

UPMC Health Plan medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of UPMC Health Plan and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

UPMC Health Plan reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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