Medicaid Impact Conference Issues

January 27, 2012

Proposal: Issue # 1

Proposal Name:	Genetic Testing for Cancer Risk
Brief Description of Proposal:	Provide funds for Medicaid to open new codes and reimburse Myriad Labs for genetic tests to detect genetic mutations indicating that patients are at higher risk of developing certain types of cancer.
Proposed State Fiscal Year: 00/00	2012-13
Proposed Start Date: 00/00/0000	08/01/2012
If not July 1, start date; please explain.	Handbook needs to be updated and the new codes need to be activated in FMMIS.
Total Cost/(Savings)/{Revenue}:	$687,500
Bureau(s) Responsible for Administration:	Medicaid Services

Key Elements:	**Yes;No;N/A**	**Explanation and Time Frame**
I. Anticipated implementation time line and process.		Rule changes are needed.
II. Will this proposal require a change in Florida Statute?	No	
III. Will this proposal require a State Plan Amendment?	No	
IV. Will this require the Procurement Process?	No	
V. Will this proposal require an administrative rule?	Yes	Handbook needs to be updated with new codes and rates for the tests and provide instruction for billing.
VI. Will this proposal require a Federal waiver or modification to an existing waiver?	No	
VII. Will this proposal require additional staffing?	No	
VIII. Is there a previous or concurrent Analysis by the Agency?	Yes	Bill Analysis
IX. Is this proposal included in the current Governors recommendations?	No	

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Analysis: **Issue # 1 Cont.**

Lead Analyst:	Mike Bolin
Secondary Analyst:	MPA
Assumptions (Data source and methodology):	Myriad Labs
FY Impacted by Implementation:	2012-13
Date Analysis Completed:	

Funding Sources:	**Start Year**	**Additional Year**	**Annualized**
Number of Months in the Analysis:	**11**	**N/A**	**N/A**
Total (Savings) Cost of Proposal:	**$687,500**		**$750,000**
General Revenue:	**$290,606**		**$317,025**
Administrative Trust Fund:	**($0)**		
Medical Health Care Trust Fund:	**$396,894**		**$432,975**
Refugee Assistance Trust Fund:	**($0)**		
Tobacco Settlement Trust fund:	**($0)**		
Grants and Donation Trust Fund:	**($0)**		
Public Medical Assistance Trust Fund:	**($0)**		
Other State Funds:	**($0)**		

Work Papers/Notes/Comments: **Issue # 1 Cont.**

(i.e. Pros, Cons; Industry Concerns; Implementation obstacles):

We are aware of only a single vendor that provides the tests proposed in this item. With a single vendor, there is no price competition.

Savings may exist in later years but are beyond the budget cycle for SFY1213.

Pros

There is potential benefit of preventing cancer in patients identified with genetically increased risk of developing cancer. The BRCA 1/2 tests have proven effective at identifying a small group of patients with genetic markers for increased risk of developing certain cancers.

Cons

According to the supplier of the test the average cost per test is approximately $3000 so there is a fiscal impact in the early years.

Prevention of cancer in patients with the BRCA 1/2 mutation requires either enhanced screening tests which Medicaid already provides to patients with a family history of these cancers or presumptive surgery such as mastectomy or oophorectomy to remove the breasts or ovaries before cancer is detected.

A negative result does not mean that a woman will not develop breast or ovarian cancer. It simply indicates that the person tested is not at increased risk for developing hereditary breast cancer or ovarian cancer related to the BRCA mutations for which he/she was tested. It is important to remember that 90-95% of breast cancers are not associated with a BRCA mutation. The risks increase with age with the bulk of these cancers occurring after age 50. The presence of a BRCA-1 or BRCA-2 mutation means that the person tested is at an increased risk for breast and/or ovarian cancer, but it does not mean that she will ever have them. Even within a family with the same BRCA mutation, not everyone will develop cancer and those that do may develop it at different times during their life. According to the National Cancer Institute (NCI), estimates of lifetime risk for breast cancer in women with BRCA-1 or BRCA-2 mutations is about 60% and estimates of risk for ovarian cancer ranges from 15% to 40%.

Finally most Medicaid recipients are children and young mothers. If this population is tested, it is very likely that they won't be Medicaid recipients by the time they reach the age where they are at significantly higher risk of developing cancer. Medicaid will have paid for the test (and perhaps the presumptive surgery) but may not realize the savings because the recipient is no longer a Medicaid recipient.

Agency staff understands the potential benefit of identifying recipients with genetically increased risk of developing cancer. The BRCA 1/2 tests have proven effective at identifying a small group of patients with genetic markers for increased risk of developing certain cancers. (See the ratings from Hayes Health Technology Assessments below for reference).

However, these tests are associated with immediate costs while the potential savings are not realized until later years. The codes assigned by CMS for these and other existing tests are already covered by Florida Medicaid for newborn screening with reimbursement rates below $20 each.

Myriad labs, the only provider of these tests, is asking the Agency to use newer codes specific to these genetic tests and reimburse an average of $3000 per test.

Using the rate of 1 test per 7000 Medicaid recipients, suggested by Myriad, produces an estimate of 250 tests with a fiscal impact on Medicaid laboratory testing of $750,000 per year. Testing 250 recipients should identify approximately 25 with the BRCA genetic mutation, of these about 10% would be expected to develop cancer in the next 10 years. **Medicare rates are consistent with the rates on which Medicaid based this fiscal impact**. The Agency expects that these tests could eventually prove to be cost effective but for near term they would have a fiscal impact.

HAYES RATING FOR GENETIC TEST:

B – For breast cancer patients from high-risk families with a known familial BRCA1/2 deleterious variant.

B – For breast cancer patients from high-risk families without a known familial BRCA1/2 deleterious variant.

B – For asymptomatic individuals from high-risk families with a known familial BRCA1/2 deleterious variant.

C – For asymptomatic individuals from high-risk families without a known familial BRCA1/2 deleterious variant.

What is a Hayes GTE Rating?

The Hayes GTE Rating system, developed by Winifred S. Hayes, Inc., reflects the quality and direction of the evidence regarding a genetic test, including safety and efficacy, impact on health outcomes, indications for use, patient selection criteria, and comparison with other technologies. The Ratings are scaled A through D1 and D2 and are defined as follows:

Rating Description

A Established benefit. Published evidence regarding analytical validity, clinical validity, and clinical utility is sufficient to support the use of the test for the application(s) under consideration.

B Some proven benefit. Published evidence regarding analytical validity, clinical validity, and clinical utility supports use of the test for the application(s) assessed. However, there are outstanding questions with respect to impact on health outcomes and/or safety.

C Potential but unproven benefit. Some published evidence regarding analytical validity and/or clinical validity supports use of the test for the application(s) assessed. However, impact on health outcomes (clinical utility) has not been demonstrated because of poor-quality studies, sparse data, conflicting study results, and/or other concerns.

D1 No proven benefit. Published evidence shows that the test lacks analytical validity, clinical validity, and/or clinical utility for the application(s) assessed.

D2 Insufficient evidence. There is insufficient published evidence to assess the analytical and/or clinical validity of the test for the application(s) assessed.

Current Medicaid Coverage of Genetic Testing:

The term “Genetic Testing” is used to cover a wide range of tests. There are three broad categories of genetic testing:

- Bio-chemical: analysis of tissues or fluids (does not involve DNA, such as Alpha-fetoprotein (AFP));
- Cytogentic: breaking cells down for a full chromosome analysis (23 from mother and 23 from father);
- Molecular: extracting DNA from the chromosomes and resulting analysis.

Current Medicaid Coverage for bio-chemical genetic testing is outlined below:

Independent Laboratory Handbook Genetic Testing

The following coverage policy is found in the Florida Medicaid Independent Laboratory Coverage and Limitations Handbook, page 2-5:

Purpose of Preconception and Prenatal Genetic Carrier Screening Laboratory Testing
Asymptomatic recipients may receive genetic carrier screening laboratory testing services to determine the recipient's risk of passing on a particular genetic mutation in X-linked and autosomal-recessive conditions. Genetic carrier screening laboratory testing services are performed to identify recipients who are themselves unaffected but are at risk for passing the condition to their off-spring.

Covered Services
Medicaid reimburses for preconception and prenatal genetic carrier screening laboratory tests that are accepted by the American College of Medical Genetics and that can be billed using Healthcare Common Procedure Coding System (HCPCS) procedure codes.

The laboratory testing method must be considered to be a proven method for the identification of a genetically-linked inheritable disease (i.e., the genotypes to be detected by a genetic test must be shown by scientifically valid methods to be associated with the occurrence of a disease, and the observations must be independently replicated and subject to peer review).

Service Requirements
Preconception and prenatal genetic carrier screening laboratory tests must be ordered by a licensed health care practitioner authorized within the scope of his practice to order genetic carrier screening laboratory tests.

The laboratory must maintain requests for the specific laboratory tests on file with copies of the report of the test results.

The recipient must be eligible for Medicaid on the date of service.

DNA-Based Preconception and Prenatal Genetic Laboratory Services Limitations
The molecular diagnostics codes are reimbursed for preconception and prenatal DNA-based genetic testing when performed as a study to determine the genetic carrier status.

Physician Services Coverage and Limitations Handbook on Genetic Testing

The following coverage policy is found in the Florida Medicaid Physician Services Coverage and Limitations Handbook, beginning on page 2-96:

Purpose of Preconception and Prenatal Genetic Carrier Screening Laboratory Testing
Asymptomatic recipients may receive genetic carrier screening laboratory testing services to determine the recipient's risk of passing on a particular genetic mutation in X-linked and autosomal-recessive conditions. Genetic carrier screening laboratory testing services are performed to identify recipients who are themselves unaffected but are at risk for passing the condition to their off-spring.

Covered Services

Medicaid reimburses for preconception and prenatal genetic carrier screening laboratory tests that are accepted by the American College of Medical Genetics and that can be billed using Healthcare Common Procedure Coding System (HCPCS) procedure codes.

The laboratory testing method must be considered to be a proven method for the identification of a genetically-linked inheritable disease (i.e., the genotypes to be detected by a genetic test must be shown by scientifically valid methods to be associated with the occurrence of a disease, and the observations must be independently replicated and subject to peer review).

Recipient Eligibility for Preconception and Prenatal Genetic Carrier Screening Laboratory Testing
Medicaid reimburses for preconception and prenatal genetic carrier screening laboratory testing services for the prospective or expecting mother and father when the following criteria are met:

- The person being tested has a direct risk factor, based on family history or ethnicity analysis, for the development of a genetically-linked inheritable disease.
- To determine person's risk of passing on a particular genetic mutation in X-linked and autosomal-recessive conditions to their off-spring.
- The person being tested is eligible for Medicaid on the date of service.

DNA-Based Preconception and Prenatal Genetic Laboratory Services Limitations
The molecular diagnostics codes are reimbursed for preconception and prenatal DNA-based genetic testing when performed as a study to determine the genetic carrier status.

Documentation Required for Preconception or Prenatal Genetic Carrier Screening Laboratory Testing
The recipient's medical records must clearly document the medical necessity for preconception or prenatal genetic carrier screening laboratory testing, which would include the direct risk factor (based on family history or ethnicity analysis) for the development of the genetically-linked inheritable disease that prompted the testing.

Screenings Related to HIV/AIDS

Florida Medicaid also reimburses, on a post authorization basis, for the Trofile assay. Trofile is a patient selection assay that is necessary to prescribe maraviroc, a new drug treating HIV/AIDS. Trofile is a clinically proven diagnostic that determines viral tropism prior to initiating a drug regimen that includes maraviroc.

Newborn Screenings:

Florida Medicaid reimburses the Florida Department of Health, Bureau of Laboratories for biochemical laboratory testing of Newborn Screenings per F.S. 383.14. Newborn Screenings consists of the following 35 metabolic disorders:

- Phenylketonuria- PKU
- Congenital adrenal hyperplasia- CAH
- Congenital hypothyroidism- HYPOTH
- Galactosemia (G/G)- GALT
- Hb S/Beta-thalassemia- HB S/Th
- HB S/C disease- HB S/C
- Sickle Cell Anemia- SCA
- Hearing Loss- HL

- 3-Methylcrotonyl-CoA carboxylase deficiency- 3MCC
- 3-OH 3-CH3 glutaric acuduria- HMG
- Arginosuccinic acidemia- ASA
- Mitochondrial acetoacetyl-CoA thiolase (beta-ketothiolase) deficiency- BKT
- Citrullinemia- CIT
- Glutaric acidemia type I- GA I
- Homocystinuria- HCY
- Isovaleric acidemia- IVA
- Long-chain L-3-OH acyl-CoA dehydrogenase deficiency- LCHAD
- Maple Syrup urine disease- MSUD
- Medium chain acyl-CoA dehydrogenase deficiency- MCAD
- Methylmalonic acidemia- MMA (Cbl A,B)
- Propionic acidemia- PA (PROP)
- Tyrosinemia type I- TYR I
- Very long-chain acyl-CoA dehydrogenase deficiency- VLCAD
- Carnitine/Acylcarnitine translocase deficiency- CAT
- Carnitine palmityl transferase deficiency type I- CPT-1
- Carnitine palmityl transferase deficiency type II- CPT-2
- Multiple acyl-CoA dehydrogenase deficiency- GA II
- Short chain acyl-CoA dehydrogenase deficiency- SCAD
- Tyrosinemia type II- TYR II
- Biotinidase deficiency- BIOT
- Carnitine uptake defect- CUD
- Methylmalonic acidemia (mutase deficiency)- MUT
- Multiple carboxylase deficiency- MCD
- Trifunctional protein deficiency- TFP
- Cystic Fibrosis- CF

Medicaid Impact Conference Issues

January 27, 2012

Proposal: Issue #2

Proposal Name:	Removal of GR from Prepaid Health Plan Capitations for IGT Portion of the Medicaid Hospital Rates
Brief Description of Proposal:	Provide an estimated impact of proportionally splitting IGTs between the hospital line and prepaid health plan line.
Proposed State Fiscal Year: 00/00	2012-13
Proposed Start Date: 00/00/0000	09/01/2012
If not July 1, start date; please explain.	This is the effective date of prepaid capitation rates.
Total Cost/(Savings)/{Revenue}:	($596,040,307)
Bureau(s) Responsible for Administration:	Medicaid Program Analysis and Program Finance

Key Elements:	**Yes;No;N/A**	**Explanation and Time Frame**
I. Anticipated implementation time line and process.		
II. Will this proposal require a change in Florida Statute?	Yes	s. 409.908
III. Will this proposal require a State Plan Amendment?	No	
IV. Will this require the Procurement Process?	No	
V. Will this proposal require an administrative rule?	No	
VI. Will this proposal require a Federal waiver or modification to an existing waiver?	No	
VII. Will this proposal require additional staffing?	No	
VIII. Is there a previous or concurrent Analysis by the Agency?	No	
IX. Is this proposal included in the current Governors recommendations?	No	

Medicaid Impact Conference Issues

January 27, 2012

Analysis: **Issue #2 Cont.**

Lead Analyst:	MPA & MPF
Secondary Analyst:	
Assumptions (Data source and methodology):	SSEC January 2012, Based on proposed language in s. 409.908 F.S.
FY Impacted by Implementation:	2012-13
Date Analysis Completed:	

Funding Sources:	**Start Year**	**Additional Year**	**Annualized**
Number of Months in the Analysis:	**10**	**N/A**	**12**
Total (Savings) Cost of Proposal:	**($596,040,307)**		**($623,125,200)**
General Revenue:	**($218,726,448)**		**($262,471,737)**
Administrative Trust Fund:	**($0)**		**($0)**
Medical Health Care Trust Fund:	**($345,017,354)**		**($360,653,463)**
Refugee Assistance Trust Fund:	**($0)**		**($0)**
Tobacco Settlement Trust fund:	**($0)**		**($0)**
Grants and Donation Trust Fund:	**($32,296,505)**		**($0)**
Public Medical Assistance Trust Fund:	**($0)**		**($0)**
Other State Funds:	**($0)**		**($0)**

Medicaid Impact Conference Issues

January 27, 2012

Work Papers/Notes/Comments: **Issue #2 Cont.**

(i.e. Pros, Cons; Industry Concerns; Implementation obstacles):

The use of intergovernmental transfers (IGTs) which fund exemptions and buy backs for inpatient and outpatient hospital rates shall not be used in the calculation of prepaid rate setting. Since no IGTs are provided, the prepaid rates will use the county billing rate. Prepaid health plans may negotiate contracts with hospitals to pay within 95 and 105 percent of the hospital county billing rate. This analysis assumes plans pay hospitals at the county billing rate.

To fund hospital costs that would be allowed in the prepaid rate setting, the Agency may collect IGTs and may develop capitation rates to include those allowable costs as long as they are not funded with General Revenue but funded through IGTs. Also, if IGTs are provided to fund hospital rates, then the IGT amount collected by the Agency will need to be proportionally applied to the rates for hospital inpatient and outpatient services and prepaid health plans. The amounts of IGTs used in prepaid rates for funding allowable costs must be used to enhance hospital payments.

Applying the IGTs proportionally would reduce the hospital rates assuming no increase in the level of IGTs provided for the July 1, 2011 rate setting. The assumption is that the Agency will receive the same amount of IGTs at the same level as adopted at the January 4, 2012 SSEC.

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	12/13 Projection	Calculation w/o IGTs	IGT Calculation	Proportional Share Redistribution of IGTs	Reduction w/ Proportional Share Redistribution of IGTs
HOSPITAL INPATIENT SERVICES					
MEDICAID CASELOAD	1,410,063	1,410,063	1,410,063	1,410,063	
MEDICAID UTILIZATION RATE	2.46%	2.46%	2.46%	2.46%	
MEDICAID ADMISSIONS PER MONTH	34,725	34,725	34,725	34,725	
MEDICAID DAYS PER ADMISSION	5.16	5.16	5.16	5.16	
MEDICAID PER DIEM	$1,729.23	$1,104.57	$624.66	$460.68	
MEDICAID TOTAL COST	$3,720,617,072	$2,376,597,230	$1,344,019,842	$991,193,269	
	2,151,604	2,151,604	2,151,604	2,151,604	
TOTAL COST	$3,720,617,072	$2,376,597,230	$1,344,019,842	$991,193,269	($352,826,573)
TOTAL GENERAL REVENUE	$594,520,775	$594,520,775	$0	$0	$0
TOTAL MEDICAL CARE TRUST FUND	$2,145,574,185	$1,369,054,986	$776,519,199	$572,215,874	($204,303,325)
TOTAL REFUGEE ASSISTANCE TF	$4,049,976	$4,049,976	$0	$0	$0
TOTAL PUBLIC MEDICAL ASSIST TF	$395,610,000	$395,610,000	$0	$0	$0
TOTAL GRANTS AND DONATIONS TF	$580,862,136	$13,361,493	$567,500,643	$418,977,395	($148,523,248)
	0.6387630784				
	0.553240888				
HOSPITAL OUTPATIENT SERVICES					
MEDICAID CASELOAD	1,410,063	1,410,063	1,410,063	1,410,063	
MEDICAID UTILIZATION RATE	77.26%	77.26%	77.26%	77.26%	
MEDICAID SERVICES PER MONTH	1,089,447	1,089,447	1,089,447	1,089,447	
MEDICAID UNIT COST	$77.29	$45.94	$31.35	$23.10	
MEDICAID TOTAL COST	$1,010,401,204	$600,590,342	$409,810,862	$302,021,595	
TOTAL COST	$1,010,401,204	$600,590,342	$409,810,862	$302,021,595	($107,789,267)
TOTAL GENERAL REVENUE	$148,455,889	$148,455,889	$0	$0	$0
TOTAL MEDICAL CARE TRUST FUND	$582,320,748	$345,430,197	$236,890,551	$174,357,067	($62,533,484)
TOTAL REFUGEE ASSISTANCE TF	$1,704,256	$1,704,256	$0	$0	$0
TOTAL PUBLIC MEDICAL ASSIST TF	$105,000,000	$105,000,000	$0	$0	$0
TOTAL GRANTS AND DONATIONS TF	$172,920,311	$0	$172,920,311	$127,664,528	($45,255,783)
	0.5944419248				

0.692430413

PREPAID HEALTH PLAN

CASELOAD	1,273,904	1,273,904	1,273,904	1,273,904		
UNIT COST	$223.25	$182.63	$40.62	$29.99		
TOTAL COST	$3,412,777,995	$2,791,837,050	$620,940,945	$458,431,585		
CASELOAD-MENTAL HEALTH	672,090	672,090	0	0		
UNIT COST	$34.19	$34.19	$0.00	$0.00		
TOTAL COST	$275,746,383	$275,746,383	$0	$0		
TOTAL COST	$3,688,524,378	$3,067,583,433	$620,940,945	$458,431,585	($162,509,360)	($135,424,467)
TOTAL GENERAL REVENUE	$1,062,265,365	$799,793,627	$262,471,737	$0	($262,471,737)	($218,726,448)
TOTAL OTHER STATE FUNDS	$0	$0	$0	$0	$0	$0
TOTAL MEDICAL CARE TRUST FUND	$2,121,018,506	$1,762,549,299	$358,469,208	$264,652,554	($93,816,654)	($78,180,545)
TOTAL REFUGEE ASSISTANCE TF	$14,640,507	$14,640,507	$0	$0	$0	$0
TOTAL HEALTH CARE TF	$490,600,000	$490,600,000	$0	$0	$0	$0
TOTAL GRANTS AND DONATIONS TF	$0	$0	$0	$193,779,031	$193,779,031	$161,482,526

- 9/1/12 date

Inp IGT	$567,500,643
Outp IGT	$172,920,311
HMO GR related	$262,471,737
	$1,002,892,691
	0.565863774
	0.172421549
	0.261714677
Total IGT	$740,420,954
Inp IGT	$418,977,395
Outp IGT	$127,664,528
HMO GR related	$193,779,031