Improving Access to Genomic Medicine

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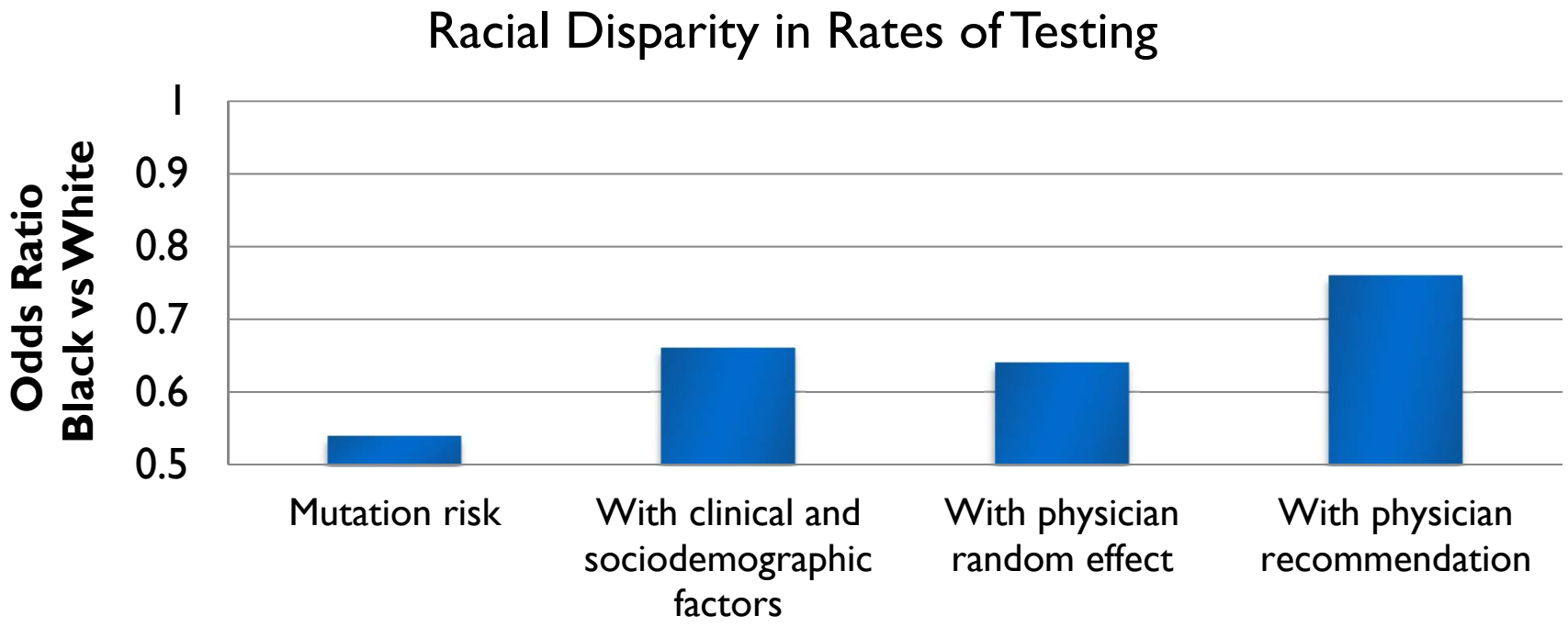
Disparities in BRCA1/2 Testing

- Black women significantly less likely to receive a physician recommendation for testing after adjusting for family history, tumor stage and characteristics, comorbidities, sociodemographic factors and attitudes about testing.



- McCarthy AM et al, JCO 2015

Addressing Differences in Recommendation

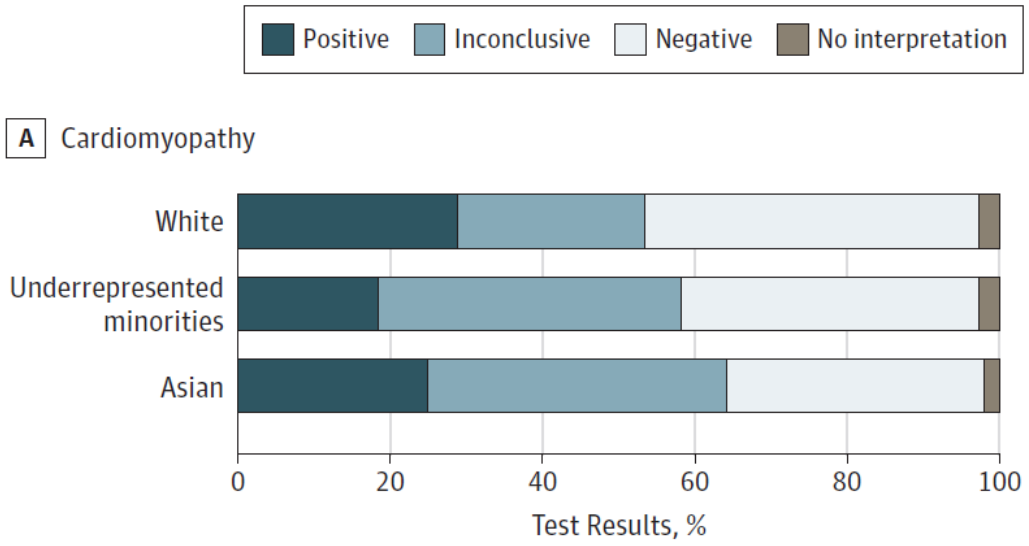
- Ensure that tools have clinical utility across groups

JAMA Cardiology | Brief Report

Association of Racial/Ethnic Categories With the Ability of Genetic Tests to Detect a Cause of Cardiomyopathy

Latrice G. Landry, PhD; Heidi L. Rehm, PhD

Figure. Genetic Testing Results by Racial/Ethnic Group



Genetic test detection rates are reduced in underrepresented minorities compared to whites and Asians ($p<0.001$) likely due to disparities in accumulating race-specific variant knowledge

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Addressing Differences in Recommendation

- Ensure that tools are effective across groups.

- Disparities in delivery of effective interventions are a quality failure.
- Focus on quality improvement:
  - Provider and patient education
  - Decision support
  - Measurement and feedback
  - Targeted process improvement projects
- Develop organizational unit to lead this and hold leadership accountable: Disparities Solution Center

Improving Access to Genomic Medicine Outside of Cancer

- Availability
  - Who will order the test and manage the results?
- Affordability
  - Who will cover the cost of the test?
- Acceptability
  - Is the patient comfortable with the service?

- How can we maximize access for all patient groups?

Heidi Rehm

- Penchansky et al. Med Care 1981; McLaughlin, Wyszewianski HSR 2002

Who will order and manage results?

- Three categories of tests:
  - Panel testing used in specialty clinics
    - Genomic lead physician(s) for each specialty
    - Patients are symptomatic
  - Predictive testing used in primary care clinics
    - Incorporation into population health strategy
    - Patients are asymptomatic
  - Whole exome testing used in multi-disciplinary clinics
    - Specialized services focused on patients with unexplained presentations
    - Patients are symptomatic and complex

	Panel Testing	Predictive Testing	WES
Who orders?	Specialist	PCP/Patient	Geneticist/ MDP
Who counsels?	In house	???	In house
Who does the test?	External/Internal	External	Internal
Who interprets?	Lab	Lab	Genomics service
Who manages results?	Specialist	PCP/Specialist	???

Equity concerns:

- *Language*
- *Continuity*
- *Risk information*
- *Provider resources*
- *Perceptions of clinical utility*
- *Actual clinical utility*

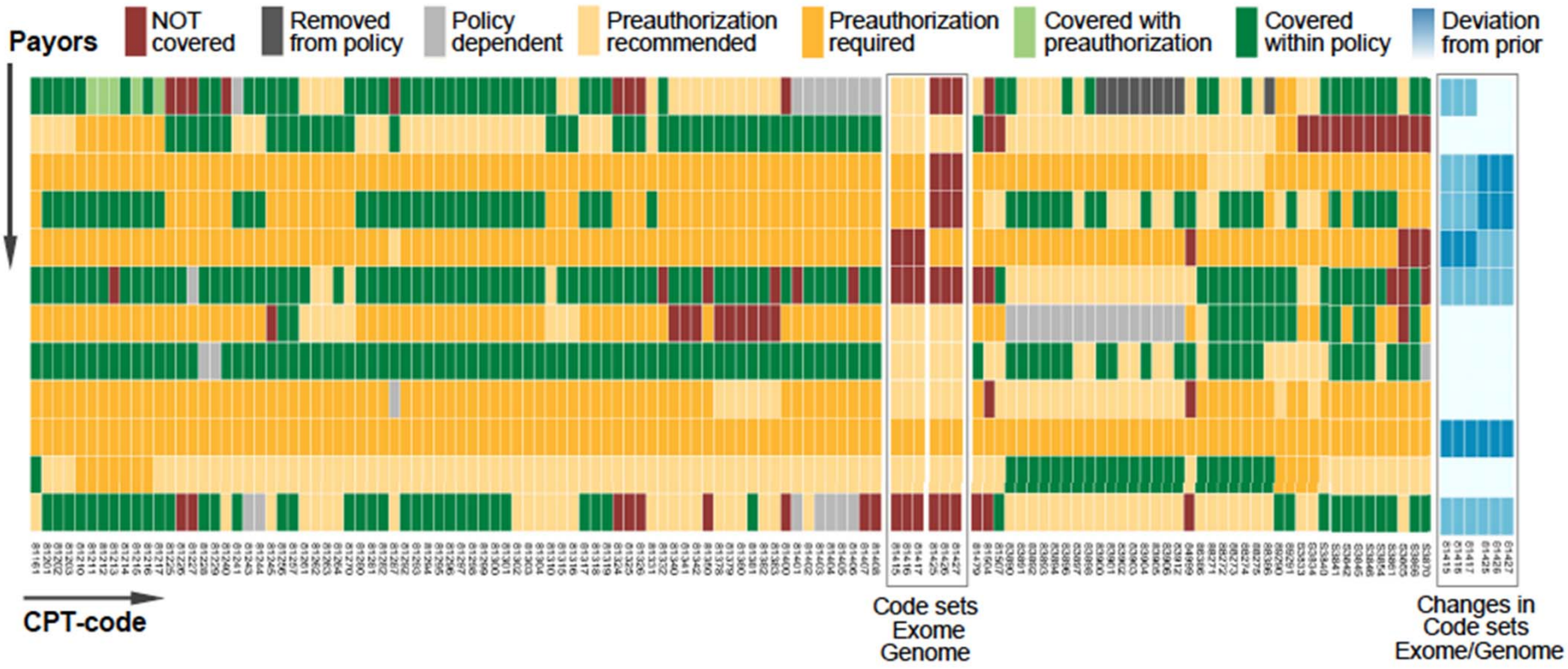
Developing a Genomics Service

- Multiple roles in supporting delivery
  - Identification of appropriate test
  - Link to genetic counseling
  - Interpretation of results
  - Referral for management discussions
  - Variant reclassification
- Focus on diverse populations
  - Community engagement
  - Patient engagement
  - Educational tools and activities
  - Language and interpreter services
  - Navigation
  - Financial support

Who will pay for the test?

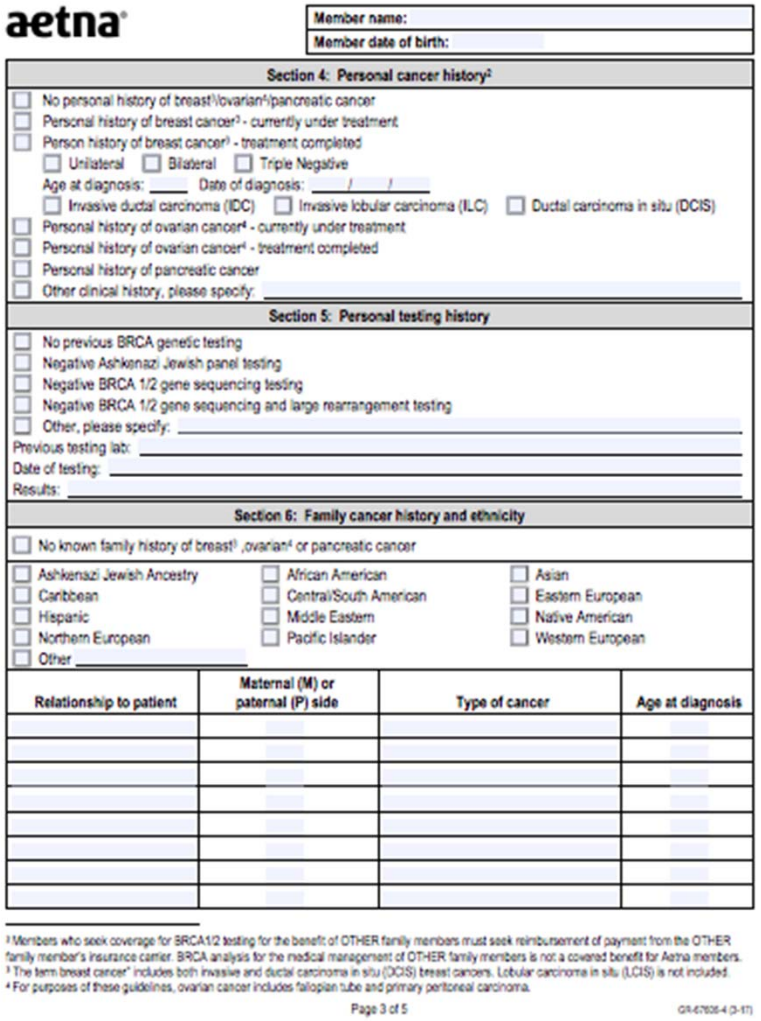
- Major challenge with insurance coverage

Heat Map Across 12 Payors in Boston Region



- Lennerz et al. J Mol Diagnostics 2016

Process for Commercial Payors Can Be Burdensome



aetna

Member name:
Member date of birth:

Section 4: Personal cancer history[2]

- ☐ No personal history of breast[1]/ovarian[4]/pancreatic cancer
- ☐ Personal history of breast cancer[3] - currently under treatment
- ☐ Person history of breast cancer[3] - treatment completed
  - ☐ Unilateral ☐ Bilateral ☐ Triple Negative
  - Age at diagnosis: ____ Date of diagnosis: ____/____/____
  - ☐ Invasive ductal carcinoma (IDC) ☐ Invasive lobular carcinoma (ILC) ☐ Ductal carcinoma in situ (DCIS)
- ☐ Personal history of ovarian cancer[4] - currently under treatment
- ☐ Personal history of ovarian cancer[4] - treatment completed
- ☐ Personal history of pancreatic cancer
- ☐ Other clinical history, please specify: _____

Section 5: Personal testing history

- ☐ No previous BRCA genetic testing
- ☐ Negative Ashkenazi Jewish panel testing
- ☐ Negative BRCA 1/2 gene sequencing testing
- ☐ Negative BRCA 1/2 gene sequencing and large rearrangement testing
- ☐ Other, please specify: _____

Previous testing lab: _____
Date of testing: _____
Results: _____

Section 6: Family cancer history and ethnicity

☐ No known family history of breast[1] ,ovarian[4] or pancreatic cancer

☐ Ashkenazi Jewish Ancestry	☐ African American	☐ Asian
☐ Caribbean	☐ Central/South American	☐ Eastern European
☐ Hispanic	☐ Middle Eastern	☐ Native American
☐ Northern European	☐ Pacific Islander	☐ Western European
☐ Other _____		

Relationship to patient	Maternal (M) or paternal (P) side	Type of cancer	Age at diagnosis

[1] Members who seek coverage for BRCA1/2 testing for the benefit of OTHER family members must seek reimbursement of payment from the OTHER family member's insurance carrier. BRCA analysis for the medical management of OTHER family members is not a covered benefit for Aetna members.
[3] The term breast cancer includes both invasive and ductal carcinoma in situ (DCIS) breast cancers. Lobular carcinoma in situ (LCIS) is not included.
[4] For purposes of these guidelines, ovarian cancer includes fallopian tube and primary peritoneal carcinoma.

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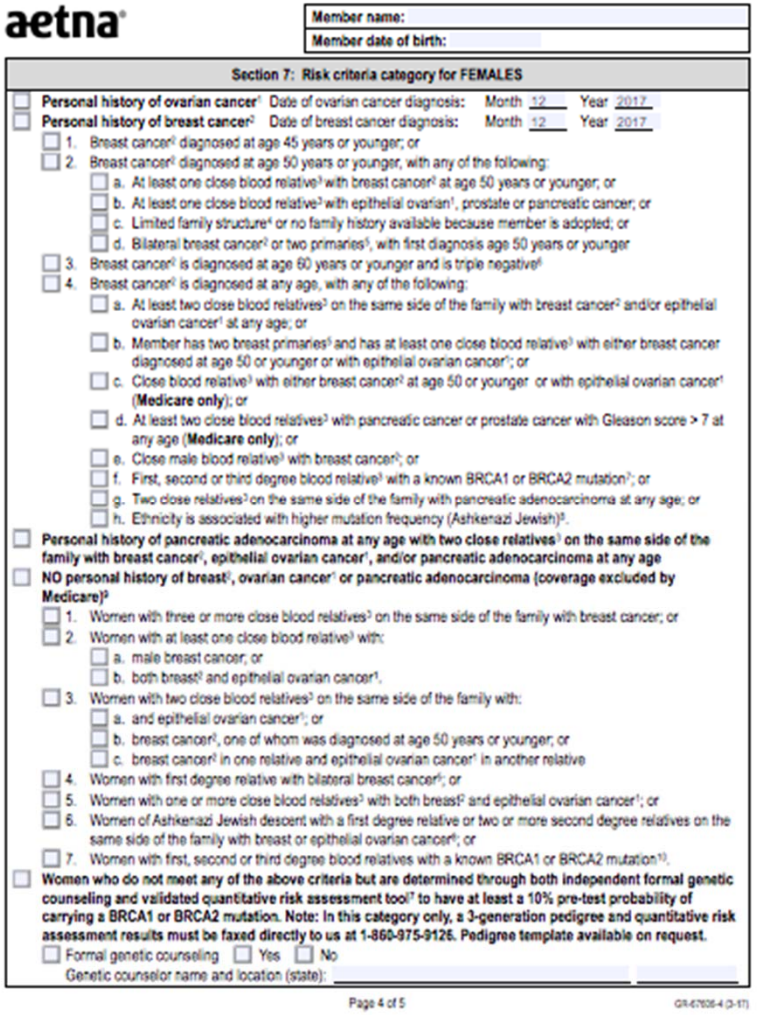

aetna

Member name:
Member date of birth:

Section 7: Risk criteria category for FEMALES

- ☐ **Personal history of ovarian cancer[1]** Date of ovarian cancer diagnosis: Month 12 Year 2017
- ☐ **Personal history of breast cancer[2]** Date of breast cancer diagnosis: Month 12 Year 2017
- ☐ 1. Breast cancer[2] diagnosed at age 45 years or younger; or
- ☐ 2. Breast cancer[2] diagnosed at age 50 years or younger, with any of the following:
  - ☐ a. At least one close blood relative[3] with breast cancer[2] at age 50 years or younger; or
  - ☐ b. At least one close blood relative[3] with epithelial ovarian[1], prostate or pancreatic cancer; or
  - ☐ c. Limited family structure[4] or no family history available because member is adopted; or
  - ☐ d. Bilateral breast cancer[2] or two primaries[5], with first diagnosis age 50 years or younger
- ☐ 3. Breast cancer[2] is diagnosed at age 60 years or younger and is triple negative[6]
- ☐ 4. Breast cancer[2] is diagnosed at any age, with any of the following:
  - ☐ a. At least two close blood relatives[3] on the same side of the family with breast cancer[2] and/or epithelial ovarian cancer[1] at any age; or
  - ☐ b. Member has two breast primaries[5] and has at least one close blood relative[3] with either breast cancer diagnosed at age 50 or younger or with epithelial ovarian cancer[1]; or
  - ☐ c. Close blood relative[3] with either breast cancer[2] at age 50 or younger or with epithelial ovarian cancer[1] (**Medicare only**); or
  - ☐ d. At least two close blood relatives[3] with pancreatic cancer or prostate cancer with Gleason score > 7 at any age (**Medicare only**); or
  - ☐ e. Close male blood relative[3] with breast cancer[2]; or
  - ☐ f. First, second or third degree blood relative[3] with a known BRCA1 or BRCA2 mutation[7]; or
  - ☐ g. Two close relatives[3] on the same side of the family with pancreatic adenocarcinoma at any age; or
  - ☐ h. Ethnicity is associated with higher mutation frequency (Ashkenazi Jewish)[8].
- ☐ **Personal history of pancreatic adenocarcinoma at any age with two close relatives[3] on the same side of the family with breast cancer[2], epithelial ovarian cancer[1], and/or pancreatic adenocarcinoma at any age**
- ☐ **NO personal history of breast[2], ovarian cancer[1] or pancreatic adenocarcinoma (coverage excluded by Medicare)[9]**
  - ☐ 1. Women with three or more close blood relatives[3] on the same side of the family with breast cancer; or
  - ☐ 2. Women with at least one close blood relative[3] with:
    - ☐ a. male breast cancer; or
    - ☐ b. both breast[2] and epithelial ovarian cancer[1].
  - ☐ 3. Women with two close blood relatives[3] on the same side of the family with:
    - ☐ a. and epithelial ovarian cancer[1]; or
    - ☐ b. breast cancer[2], one of whom was diagnosed at age 50 years or younger; or
    - ☐ c. breast cancer[2] in one relative and epithelial ovarian cancer[1] in another relative
  - ☐ 4. Women with first degree relative with bilateral breast cancer[2]; or
  - ☐ 5. Women with one or more close blood relatives[3] with both breast[2] and epithelial ovarian cancer[1]; or
  - ☐ 6. Women of Ashkenazi Jewish descent with a first degree relative or two or more second degree relatives on the same side of the family with breast or epithelial ovarian cancer[2]; or
  - ☐ 7. Women with first, second or third degree blood relatives with a known BRCA1 or BRCA2 mutation[10].
- ☐ **Women who do not meet any of the above criteria but are determined through both independent formal genetic counseling and validated quantitative risk assessment tool[7] to have at least a 10% pre-test probability of carrying a BRCA1 or BRCA2 mutation. Note: In this category only, a 3-generation pedigree and quantitative risk assessment results must be faxed directly to us at 1-860-975-9126. Pedigree template available on request.**
  - ☐ Formal genetic counseling ☐ Yes ☐ No
  - Genetic counselor name and location (state): _____

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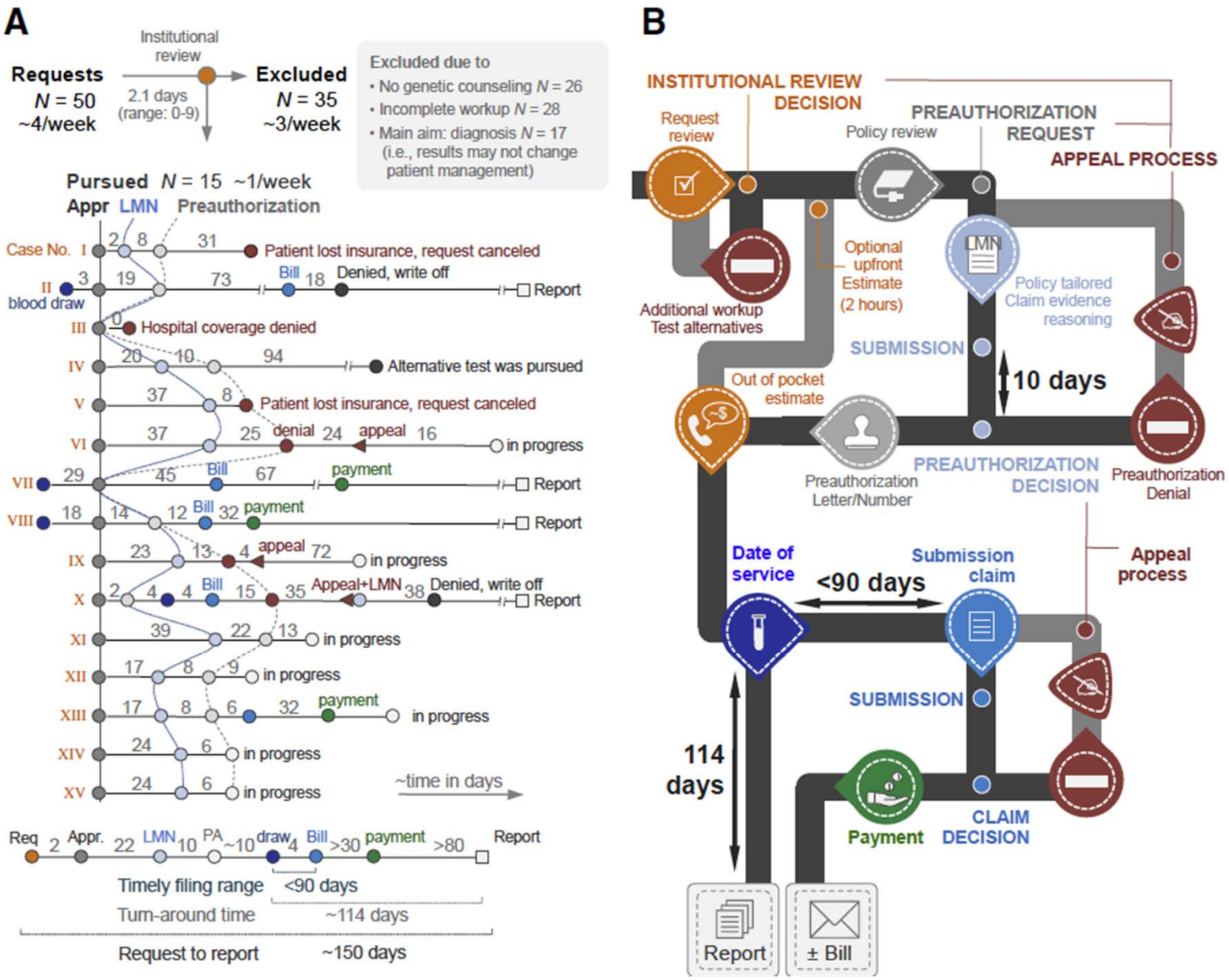


Lennerz et al. J Mol Diagnostics 2016

Hi Katrina

To make things a little easier to follow, here is a brief summary:

1. Change of managed care provider via financial services.
2. Prior authorization for confirmatory single-gene sequencing for 3 targets
3. Discussion of testing and next steps regarding continued care and possible bone marrow transplant

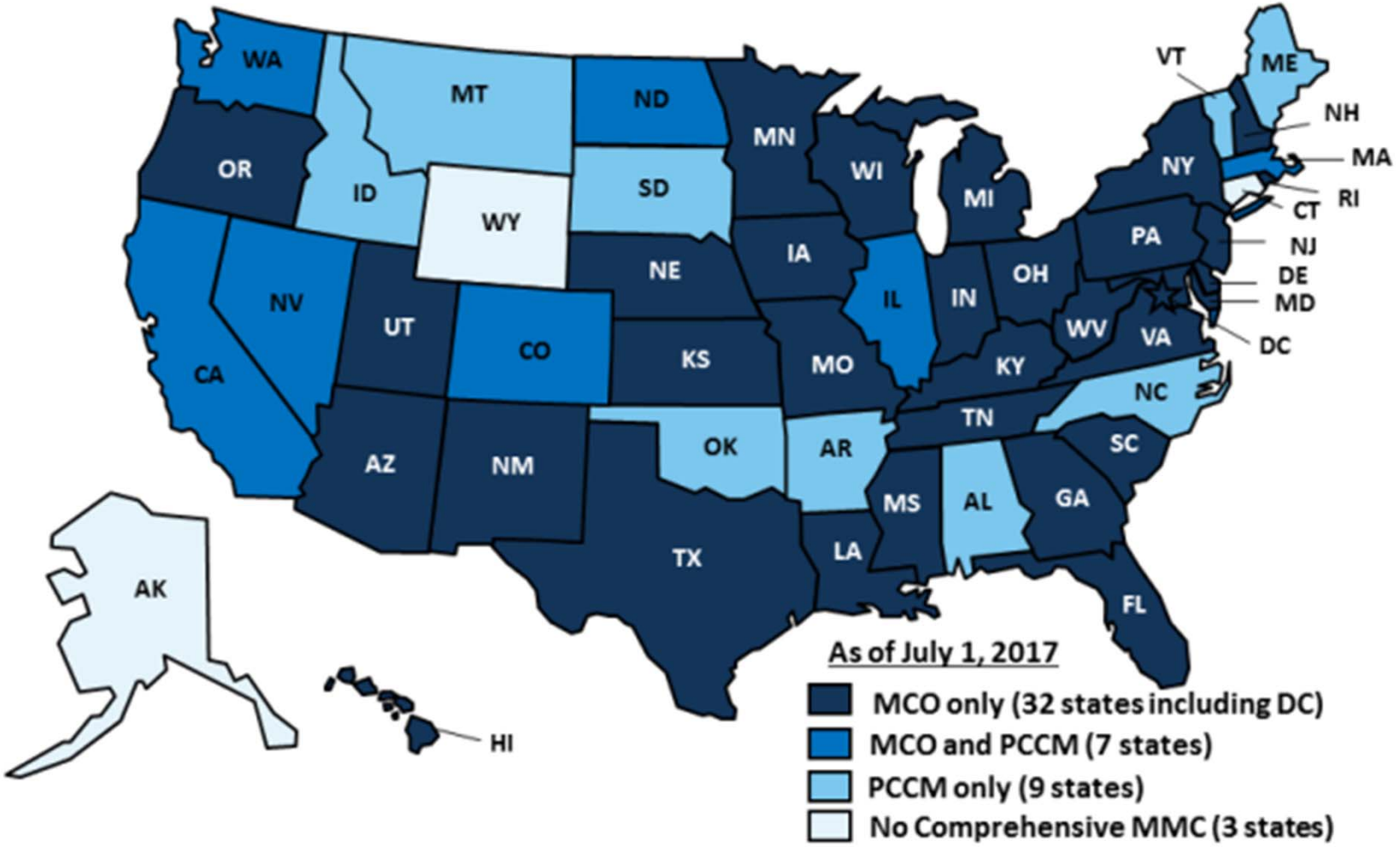
Re 1. The patient currently has an out of network primary care provider (PCP) – and financial services (**Karla Ortha**) is helping him to switch PCP to **Dr. Jacob (Jake) Rosenberg** (now also in CC) so we can see the patient here at MGH.
Re 2. Prior authorization is initiated (via **Ellen Babine** and **Amy Crosby**). Fallon (Payor) knows about the urgency of the request and relevance for management. We expect to hear back early next week so we can obtain the sample on Wednesday (next appointment of the patient). Related to this, is that date of service is **after** date of prior authorization and followed by expedited sample transfer to LMM (**Heidi Rehm**).
Re 3. The next steps in clinical management, assuming genetic variants are confirmed (and in the unlikely event that none or not all variants will be confirmed) will (likely) require continued care at MGH – and according to **David Sykes** (via Rajesh) **potentially a bone marrow transplantation**.

ACTION ITEMS:
Patient can be scheduled.
Date of service will be within the approved range OP 0032405297 valid 3/20/18-3/20/19.
You will need to fill out the LMM req.
David we can help with coordinating blood tube transport to LMM.

1) Change in coverage from MH Fallon to Partners ACO.
According to Heather (was on the phone with her now), the patient now has switched effected 4/1/2018 and now has a new PCP (Dr. Siamak M
(Briefly MGH was not 'in-network' for MH Fallon, but is 'in-network' with Partners ACO).
Now he is Partners Health Care Choice ACO administrated via MassHealth Network: the switch was active 3/31st.

2) prior authorization with Fallon.
Hi,
Just talked with Fallon – they mentioned they had communicated the authorization to Dr. Armstrong (but maybe via fax? So not surprised the message d
He is **approved for both CPTs – OP 0032405297 valid 3/20/18-3/20/19.**
I will follow up with PFS as the patient still needs to change his plan, but has Fallon for now!

Comprehensive Medicaid Managed Care Models in the States, 2017



NOTES: CA has a small PCCM program operating in LA County for those with HIV. Three states (SC, TX and WY) use PCCM authority to operate specialized care management programs or to make PMPM payments in a Patient Centered Medical Home program; these three are not counted here as a PCCM.

SOURCE: KFF survey of Medicaid officials in 50 states and DC conducted by HMA, October 2017.

Managing Health Care Costs

- Create effective tools and systems for delivering them
- Standardize billing models = e.g. DRGs
- Develop a clinical workforce and reimbursement for their services
- Engage quality improvement systems
- Participate in the development of Medicaid ACOs including policies and other accountable care models