

Resolution No. 53 New

Report: None Date Submitted: September 2017

Submitted By: Ninth Trustee District

Reference Committee: B (Dental Benefits, Practice and Related Matters)

Total Net Financial Implication: None Net Dues Impact: _____

Amount One-time _____ Amount On-going _____ FTE 0

ADA Strategic Plan Objective: Membership-Obj. 1: Leaders and Advocates in Oral Health

How does this resolution increase member value: See Background

1 GENETIC TESTING FOR RISK ASSESSMENT

2 The following resolution was submitted by the Ninth Trustee District and transmitted on September 19,
3 2017, by Ms. Michelle Nichols-Cruz, governance manager, Michigan Dental Association.

4 **Background:** Risk-based benefit plan design is growing in popularity with plan administrators, plan
5 purchasers and dental care providers. It allows for targeting benefits for care and thus access to care, for
6 those individuals at greatest health risk and it assures optimal use of limited plan resources to provide for
7 the best outcomes.

8 Typically a patient’s level of risk is assessed through generally accepted clinical markers or risk
9 assessment tools that have validity and reliability. This is important because inaccurate assignment of a
10 patient’s risk status or that of an entire population within a plan could result in adverse health outcomes if
11 access to needed care is restricted by the plan benefit allowances based on faulty conclusions.

12 Such was the case with a risk-based plan promoted by Delta Dental Plan of Michigan (DDPM), called
13 RightSize. This plan used a genetic test called PerioPredict to determine a patient’s risk for periodontitis.

14 DDPM supported a study by the University of Michigan and hailed its findings to assert that the
15 PerioPredict genetic test identifies the “periodontal gene.” The Michigan study was cited in literature
16 introducing Delta Dental’s new risk plan that limited dental cleanings to one annually and allowed access
17 to additional cleanings if the patient tested positive to the genetic test or had other risk markers such as a
18 history of diabetes or history of periodontal care. Additionally, the University of Michigan study concluded
19 that using this genetic test in such a plan design would save the dental plan roughly \$37 per patient
20 annually.

21 Instituting such a plan responds to marketplace pressures to contain plan costs and promotes an
22 impression of integrated health plan design. Delta Dental was the only payer known to use this genetic
23 test within a benefit plan design. In fact, other payers chose not to benefit the test or recognize its
24 conclusions. United Healthcare’s 2017 Dental Clinical Policy stated “The clinical utility of genetic testing
25 for susceptibility to periodontal diseases has not been established. Additionally, there is a lack of
26 objective, high quality clinical evidence to support these tests.”

27 It should also be noted that DDPM’s parent organization was an investor in the test’s manufacturer
28 Interleukin Genetics Inc., creating what could be viewed as a conflict of interest to promote adoption of
29 this test.

1 In March of 2015, *JADA* published an article by Dr. Scott Diehl et al that reanalyzed the data used in the
2 University of Michigan study and concluded that the genetic test was not useful in identifying individuals
3 at risk for periodontitis. Earlier this year, the ADA published "[Oral Health Topics](#)" on ADA.org that
4 concluded that no genetic test currently exists to assess risk for a patient developing periodontitis, yet
5 DDPM continued to use the test within its risk-based plan to ration access to benefits for preventive care.

6 The genetic testing community has also taken notice of this test. Recently the publication [GenomeWeb](#)
7 [published that there are serious concerns with the marketing and science behind this product](#). Recently,
8 the makers of the test, Interleukin Genetics Inc., announced its [liquidation](#) and it is assumed that their test
9 is no longer available.

10 The sponsors of this resolution recognize the value of risk-based benefit plan design and its promise of
11 appropriately directing benefit plan resources to those most in need of care. We are also hopeful that
12 genetic testing will emerge to aid in this goal. However, the sponsors of this resolution find it concerning
13 that a genetic test that had at best conflicting evidence for its validity and reliability, was used by a benefit
14 plan to restrict access to benefits for care and potentially negatively impact health outcomes.

15 Dentistry is not alone. Health professions will experience a growth of such products and tests in the
16 coming years and we will need a mechanism to assess the claims and counter claims so that we may
17 best serve our patients and advocate for the needs of the public.

18 For guidance on this issue, we may need only to look to the Centers for Medicare and Medicaid Services,
19 the largest payer of health benefits in America and a driver of trends for the benefit industry. As detailed
20 in this link, Medicare contractor Palmetto has implemented a strategy that places the burden of proof (and
21 cost) onto the manufacturer:

22 [https://www.palmettogba.com/palmetto/MolDX.nsf/DocsCat/MolDx%20Website~MolDx~Browse%20By%
23 20Topic~Technical%20Assessment~8PKRZF3404?open](https://www.palmettogba.com/palmetto/MolDX.nsf/DocsCat/MolDx%20Website~MolDx~Browse%20By%20Topic~Technical%20Assessment~8PKRZF3404?open)

24 To provide a mechanism where genetic test manufacturers and benefit plans using such tests can
25 provide assurances on validity and reliability for their program, ADA staff has suggested pursuing
26 development of standards through the American National Standards Institute (ANSI). Doing so would
27 provide needed credibility beyond that achieved through ADA policy alone, however; such a process is
28 estimated to take over two years to achieve. Thus the sponsors of this resolution would recommend a two
29 phase approach to first have Association policy on the expectations the profession would have on this
30 topic for the protection of our patients and also that the ADA would work through ANSI to have standards
31 developed through that organization.

32 **Resolution**

33 **53. Resolved**, that for the health and well-being of the public, the American Dental Association
34 believes that any payer organization using a genetic test to determine eligibility for benefit coverage
35 for specific oral healthcare services and any manufacturer of a test(s) used in such an effort must
36 publish specific information on:

- 37 • Confirmation from an independent third party agency of test validity and reliability for the
38 intended purpose
- 39 • Analysis on how this specific plan design will impact health outcomes and plan costs
- 40 • Disclosure of financial relationships between the manufacturer and payer
- 41 • Disclosure of bias and conflict of interest between the test manufacturer, investigators
42 providing evidence and literature used to promote the test and plan design and with the
43 payer organization

44 and be it further

- 1 **Resolved**, that the American Dental Association should work with the American National Standards
- 2 Institute (ANSI) to develop industry standards for these tests.

- 3 **BOARD RECOMMENDATION: Received after the September 2017 Board of Trustees meeting.**

NOTES