



# **Coding and Payment for Genomic Sequencing Procedures (GSPs) and Existing Advanced Diagnostic Laboratory Tests (ADLTs)**

Clinical Laboratory Fee Schedule Public Meeting  
July 16, 2015

Baltimore, MD

21<sup>st</sup>  
centurymedicine



# Coalition for 21<sup>st</sup> Century Medicine

The Coalition represents the world's most innovative diagnostic technology companies, clinical laboratories, researchers, physicians, venture capitalists and patient advocacy groups – all linked by a common mission: to develop and commercialize state-of-the-art diagnostics that improve patient health.



# Genomic Sequencing Procedures



## C21 Supports the 2015 Final Payment Decision for Targeted GSPs :

- For GSP codes CMS should continue to allow MAC contractors to set payment by gapfill when the Medicare contractor determines the code is payable.
- Contractors should be allowed to develop and use unique test identifiers for GSP procedures.

### Rationale:

- Local contractor determination. A wide variety of tests can be described by each GSP code, extended dialogue between the laboratory/manufacture and the entity making the coverage determination is necessary to ensure that an appropriate coverage decision is made.
- Gapfill. The GSP code category was created as a distinct code category because these codes are unlike anything else on the CLFS. Because there are no analogues in the existing CLFS, gapfill remains the best option for determining the payment amount. Consistent with the policies underlying PAMA, contractors should review commercial payer rates, among other data points, to determine Medicare payment.
- Unique test identifiers. Allowing contractors to establish and use unique test identifiers is consistent with CMS' s transparency interests: Unique test identifiers allows CMS and its contractors to identify claims submitted.

# 2016 CLFS Recommendation



- On or before January 1, 2016, CMS should adopt and publish the CPT® codes for Existing Advanced Diagnostic Laboratory Tests (ADLT) issued by the AMA
- On or before January 1, 2016, for each Existing ADLT CMS should publish the local payment rate of the MAC who issued a local coverage determination for the Existing ADLT
- These recommendations are consistent with requirements under Section 216 of the Protecting Access to Medicare Act (PAMA)

# Background



- PAMA created special payment and coding rules for certain Existing ADLTs paid by the Medicare program as of the date of enactment (04/01/2014), requiring that Existing ADLTs be assigned unique codes and that payment rates for these unique codes be publicly posted by January 1, 2016
- PAMA also created a transitional rule to allow CMS to use existing methodologies, including gapfill or crosswalk, to establish payment rates for new lab tests that had not already been priced by CMS or the MACs
- In response to PAMA, AMA put out a special stakeholder notification for existing ADLT code applications.
- As a result, eight existing ADLTs were assigned new CPT codes and are included on today's Agenda.



# ADLT Definition under PAMA

## *“(5) ADVANCED DIAGNOSTIC LABORATORY TEST DEFINED*

*In this subsection, the term ‘advanced diagnostic laboratory test’ means a clinical diagnostic laboratory test covered under this part that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and meets one of the following criteria:*

*“(A) The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result.*

*“(B) The test is cleared or approved by the Food and Drug Administration.*

*“(C) The test meets other similar criteria established by the Secretary.”*

*Soc Sec Act 1834A(d)(5)*

# Requirement for Existing ADLTs

## *“(2) Existing Tests*

*Not later than January 1, 2016, for each existing advanced diagnostic laboratory test (as so defined) and each existing clinical diagnostic laboratory test that is cleared or approved by the Food and Drug Administration for which payment is made under this part as of the date of enactment of this section, if such test has not already been assigned a unique HCPCS code, the Secretary shall –*

*(A) assign a unique HCPCS code for the test, and*

*(B) publicly report the payment rate for the test.”*

*Soc Sec Act 1834A(e)(2)*

# New Codes Effective January 1, 2016 for Existing ADLTs



- AMA issued a special stakeholder notification for ADLTs meeting the following criteria:
  - Were paid by Medicare
  - Qualify as an ADLT
- In response to the AMA, eight Existing ADLTs that meet the AMA criteria received Category I MAAA codes that will be effective January 1, 2016
- Prior to being assigned a Category I MAAA code, the MACs with jurisdiction for establishing coverage for each test determined payment rates and provided individual coding instructions to the laboratories billing for these tests



# Existing ADLTs and July Public Meeting

- CMS is required to publish a payment rate for these “Existing ADLTs” on January 1, 2016
- In the past two rate setting cycles, CMS has determined MAAA rate-setting by instructing contractors to gapfill rates when the contractor determines that a test is payable
- If CMS follows the same approach this year and leaves rate-setting for contractors to gapfill these codes next year, the PAMA requirement to publish a rate on January 1, 2016 will not be met

# Transitional Rule

## *“(i) TRANSITIONAL RULE*

*During the period beginning on the date of enactment of this section and ending on December 31, 2016, with respect to advanced diagnostic laboratory tests under this part, the Secretary shall use the methodologies for pricing, coding, and coverage in effect on the day before such date of enactment, which may include cross-walking or gapfilling methods.”*

*Soc Sec Act 1834A(i)*

# Application of Transitional Rule

- Transitional rule was intended to provide CMS the ability to price new lab tests, that had not already been priced by CMS or the MACs, in the period between PAMA passage and implementation
- CMS can use July meeting along with gapfilling or crosswalking to establish transitional payment rates until full market rates are established

# Recommendations



- On or before January 1, 2016, CMS should adopt and publish the CPT® codes for Existing ADLTs issued by the AMA
- On or before January 1, 2016, for each Existing ADLT CMS should publish the local payment rate of the MAC who issued a local coverage determination for the Existing ADLT
- To meet the PAMA publishing requirement, CMS may:
  - Publish the codes and rates in the PAMA Final Rule; or
  - Publish the codes and rates in the CLFS Final Payment Determinations for 2016





**Thank you!**