

# Interpace Diagnostics Announces New CPT Code for Reimbursement of Molecular Thyroid Test

## New CPT Code Assigned by AMA for ThyraMIR® Recognizes Distinct Attributes of Test

PARSIPPANY, N.J., Sept. 11, 2017 (GLOBE NEWSWIRE) -- Interpace Diagnostics Group, Inc. (NASDAQ:IDXG) ("Interpace" or "the Company"), a fully integrated commercial company that provides clinically useful molecular diagnostic tests and pathology services for improved patient diagnosis and management, announced today that the American Medical Association (AMA) has assigned a new, discreet CPT (Current Procedural Technology) code to facilitate reimbursement of ThyraMIR, the Company's proprietary miRNA-based molecular test for indeterminate thyroid nodules. The new code, 0018U, is associated with an official Descriptor which states, "Oncology (thyroid), microRNA profiling by RT-PCR of 10 miRNA sequences, utilizing fine needle aspirate, algorithm reported as a positive or negative result for moderate to high risk of malignancy." The AMA Technology Assessment Group (TAG) conducted a formal review of the Company's submission as part of the decision-making process, which included direct participation in a discussion with the Committee.

CPT codes are used by medical practitioners including, physicians, laboratories, and other healthcare providers to report their services to payers and seek reimbursement. This standardized national system of identification provides a uniform language for reporting healthcare procedures and services. The existence of this unique code for ThyraMIR will simplify and expedite the process for Interpace in submitting claims and securing reimbursement.

The approval was part of the AMA's PLA (Proprietary Laboratory Analysis) program which allows providers the opportunity to make a case that their technology's characteristics are distinct enough from other tests that a discreet CPT code for billing payers is warranted. PLA codes were established under the PAMA (Protecting Access to Medicare Act) in 2014 allowing single source laboratories with Advanced Diagnostic Laboratory Tests (ADLTs) to apply for codes that recognize the sole source and esoteric nature of their assays. ThyraMIR meets the definition of an ADLT under PAMA.

Now that ThyraMIR has its own distinct code, we believe that obtaining CPT coding methodology for the ThyGenX - ThyraMIR combination test should be more straightforward. ThyGenX is billed using a standard code the AMA created in 2015 for all tests with specific common characteristics, namely they are run on a Next Generation Sequencing platform and contain a certain number of genetic markers. ThyGenX – ThyraMIR represents the only test in the market that combines the rule-in properties of next-generation sequencing of a patient's DNA and RNA, with rule-out capabilities of a micro-RNA classifier to provide

physicians with clinically actionable test results. Since 2015 Interpace has conducted over 15,000 ThyraMIR tests for nearly 400 physicians and hospitals nationwide.

According to the American Cancer Society, thyroid cancer is the most rapidly increasing cancer in the U.S., tripling in the past three decades. Most physicians have traditionally recommended thyroid surgery where thyroid nodule biopsy results are indeterminate, not clearly benign or malignant following traditional cytopathology review; however, 70%-80% of these surgical outcomes are ultimately benign. Molecular testing using ThyGenX – ThyraMIR has been shown to reduce the rate of unnecessary surgeries in indeterminate cases.

Jack E. Stover, President and CEO of Interpace Diagnostics stated, "We are incredibly pleased that the AMA has assigned us our own CPT code for ThyraMIR in recognition of its distinction among other tests in the market." He further noted, "This important reimbursement milestone combined with our other recent announcements regarding increased coverage of ThyraMIR, will enable the Company to fully leverage the increasing access of the test to both patients and physicians."

### About Thyroid Nodules, ThyGenX and ThyraMIR testing

According to the American Thyroid Association, approximately 15% to 30% of the 525,000 thyroid fine needle aspirations (FNAs) performed on an annual basis in the U.S. are indeterminate for malignancy based on standard cytological evaluation, and thus are candidates for ThyGenX and ThyraMIR.

ThyGenX and ThyraMIR reflex testing yields high predictive value in determining the presence and absence of cancer in thyroid nodules. The combination of both tests can improve risk stratification and surgical decision-making when standard cytopathology does not provide a clear diagnosis for the presence of cancer.

ThyGenX utilizes state-of-the-art next-generation sequencing (NGS) to identify more than 100 genetic alterations associated with papillary and follicular thyroid carcinomas, the two most common forms of thyroid cancer. ThyraMIR is the first microRNA gene expression classifier. MicroRNAs are small, non-coding RNAs that bind to messenger RNA and regulate expression of genes involved in human cancers, including every subtype of thyroid cancer. ThyraMIR measures the expression of 10 microRNAs. Both ThyGenX and ThyraMIR are covered by both Medicare and many Commercial insurers.

#### **About Interpace Diagnostics Group, Inc.**

Interpace Diagnostics is a fully integrated commercial company that provides clinically useful molecular diagnostic tests and pathology services to evaluate the risk of cancer by leveraging the latest technology in personalized medicine for better patient diagnosis and management. The Company currently has three commercialized molecular tests; PancraGEN<sup>®</sup> for the diagnosis and prognosis of pancreatic cancer from pancreatic cysts; ThyGenX<sup>®</sup>, for the diagnosis of thyroid cancer from thyroid nodules utilizing a next generation sequencing assay and ThyraMIR<sup>®</sup>, for the diagnosis of thyroid cancer from thyroid nodules utilizing a proprietary gene expression assay. Interpace Diagnostics' mission is to provide personalized medicine through molecular diagnostics and innovation to

advance patient care based on rigorous science.

#### About the AMA

The American Medical Association (AMA) is the largest national organization of physicians and other caregivers whose primary goal is to promote the art and science of medicine and the betterment of public health. Their vision is to enhance the delivery of care and enable physicians and health teams to partner with patients to achieve better health. Approximately 30% of physicians in the U.S. are members of the Association. As part of its mission, the AMA establishes Current Procedural Coding (CPT) codes for all services performed by a wide variety of provider types including physicians, hospitals, laboratories, home health providers, durable medical equipment providers, radiology services, and many others. This is necessary to ensure conformity by all providers to a common standard of defining the services they perform.

#### **Forward Looking Statements**

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, relating to the Company's future financial and operating performance. The Company has attempted to identify forward looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forwardlooking statements. These statements are based on current expectations, assumptions and uncertainties involving judgments about, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the Company's control. These statements also involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results to be materially different from those expressed or implied by any forward-looking statement. Known and unknown risks, uncertainties and other factors include, but are not limited to, the Company's ability to adequately finance the business, its ability to restructure its liabilities and other obligations, the market's acceptance of its molecular diagnostic tests, its ability to retain or secure reimbursement, its ability to secure additional business and generate higher profit margins through sales of its molecular diagnostic tests, in-licensing or other means, projections of future revenues, growth, gross profit and anticipated internal rate of return on investments and its ability to maintain its NASDAQ listing. Additionally, all forward-looking statements are subject to the risk factors detailed from time to time in the Company's filings with the SEC, including without limitation, the Annual Report on Form 10-K filed with the SEC on March 31, 2017 and the amendment on Form 10-K/A filed on April 28, 2017, the company's Quarterly Reports on Form 10-Q for the guarter ended March 31, 2017 filed with the SEC on May 12, 2017 and for the guarter ended June 30, 2017 filed with the SEC on August 10, 2017, and the Company's Registration Statement on Form S-1 (333-218140, the "registration statement") initially filed with the SEC on May 22, 2017. Because of these and other risks, uncertainties and assumptions, undue reliance should not be placed on these forward-looking statements. In addition, these statements speak only as of the date of this press release and, except as may be required by law, the Company undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

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