Date: January 15, 2016

To: The clinical laboratories and hospital laboratories that perform genetic and molecular diagnostic testing for our members

Please share with those in your organization who are responsible for clinical oversight of lab testing or compliance and those who bill for genetic and molecular diagnostic testing

From: David Bishop, Regional Manager Provider Relations

Subject: Effective April 18, 2016: Register Clinical Laboratories and Molecular Diagnostic Tests in the McKesson Diagnostics Exchange (DEX)

Use DEX to Register Genetic and Molecular Diagnostic Tests

To better understand what genetic and molecular diagnostic tests are being ordered and why they are being performed, we are requiring testing laboratories to register with McKesson Diagnostics Exchange™ (DEX) and submit molecular tests for a unique Z-Code Identifier and include them on your claims submission. This will help us better identify and evaluate tests, and apply policy.

When you perform genetic or molecular diagnostics tests, you want to know if they will be covered. The lack of specificity of genetic and molecular diagnostic testing codes can be problematic for providers who order these tests and the labs performing them. This is also challenging for payers who are responsible for coverage decisions and managing the cost of care on behalf of our employer customers.

We will launch this phase of our genetic and molecular diagnostic testing program to help address these issues. In this phase, you will register the genetic and molecular diagnostic tests you perform using an online data exchange. This registration process can start now and must be completed by April 18, 2016. In the future, we expect to use this exchange for servicing providers to look up genetic and molecular diagnostic tests to see if they will be covered for our members before they are performed.

Background:

We understand that genetic and molecular diagnostic tests, when appropriately used, can help confirm a diagnosis, determine the risk of developing a specific disease or health condition, offer greater insight on therapeutic and preventive options for treatment, and monitor response to certain pharmacogenetic agents.

Advances in science and technology are driving the rapid development of new genetic tests and molecular diagnostic services, resulting in increasing costs to our customers. The rapid growth of the industry and number of available tests can make it difficult for physicians to know which test to order and whether the test is the most appropriate for a patient. These factors, with the following issues, challenge health plans’ ability to identify and evaluate tests, and apply policy:

- Inadequate published evidence to support appropriate use and guide coverage for many molecular diagnostic services and genetic tests.
- Lack of specific billing codes resulting in use of CPT codes that describe lab procedures but do not indicate what condition or trait is being assessed. These codes reflect the multiple steps involved in the testing but do not provide information about the kinds of tests being performed and why, which may lead to over- or under-payment for these services.
Timelines:
You may start registration as early as February 1, 2016. Completion timelines are as follows (also defined in the table below):

- Register your laboratory organization in DEX by **April 18, 2016**
- Top 10 tests by volume be submitted no later than **May 2, 2016** for Z-Code Identifiers
- Deadline for all test submissions for Z-Codes is **June 6, 2016**
- Z-Codes to be included on claims will be mandatory for payment as of **August 8, 2016**

*Placing Z-Codes on your claims prior to this date is voluntary.*

We will have a liaison to assist you with both the registration process and test submissions.

**Instructions for Servicing Laboratories: Get Started February 1, 2016!**

New to McKesson Diagnostics Exchange (DEX):
We are asking **servicing laboratories** to register your laboratory organization in DEX by **April 18, 2016**. Once registered, you will submit your genetic and molecular tests for Z-Code Identifiers. From the time you submit, if all required information is included, a Z-Code Identifier will be assigned within 30 days. We are requesting that your top 10 tests by volume be submitted no later than **May 2, 2016** for Z-Code Identifiers. We will have a liaison to assist you with both the registration process and test submissions. Deadline for all test submissions for Z-Codes Identifiers as defined in the table below is **June 6, 2016**.

Existing DEX Laboratory:
If you are currently a registered lab in DEX, you will need to update your organization to participate with Paramount by navigating within DEX to **My Organization -> Payer Options** tab. Once this is completed, please continue to submit new tests for Z-Code Identifiers as you have done in the past. If you have any questions, we will have a liaison to assist you with the test submissions.

Claim Submission for All Laboratories:
In addition, we will be asking for Z-Code Identifiers to be included on your 837 electronic claim submission no later than **August 8, 2016**.

**Scope of Testing:**

<table>
<thead>
<tr>
<th>Test Group</th>
<th>CPT Code Range</th>
<th>Date Required for Lab/Test Registration</th>
<th>Date Required for Z Code Identifiers on Claim Submissions</th>
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</thead>
<tbody>
<tr>
<td><strong>Group 1:</strong></td>
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<tr>
<td>MoPath Tier 1</td>
<td>81161, 81200-81383</td>
<td>Lab Registration – April 18,2016</td>
<td>August 8, 2016</td>
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<tr>
<td>MoPath Tier 2</td>
<td>81400-81408</td>
<td>Top 10 Tests Registration – May 2,2016</td>
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<tr>
<td>MoPath Misc</td>
<td>81500-81599</td>
<td>Remaining Tests Registration – June 6, 2016</td>
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<tr>
<td>MAAA codes</td>
<td>81410, 81411, 81415…81471</td>
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<tr>
<td>NEW 2015 GSP codes</td>
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<tr>
<td><strong>Group 2 : Future</strong></td>
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<tr>
<td>IHC</td>
<td>88341, 88342, 88344</td>
<td>Q 4 2016</td>
<td>TBD</td>
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<td><strong>Group 3: Future</strong></td>
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<tr>
<td>Flow Cytometry,</td>
<td>88182-88189</td>
<td>Q 4 2016</td>
<td>TBD</td>
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<tr>
<td>Molecular Cytogenetics</td>
<td>88271-88275</td>
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<tr>
<td>Morphometric Analysis, FISH</td>
<td>88360-88368</td>
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In 4th quarter 2016, you may need to register tests for IHC, Flow Cytometry, FISH, and others. In addition, we will be asking for Z-Code Identifiers to be included on your claim submission. Our expectation is that you will provide us with information on the tests you perform now and at any time in the future if you add a genetic or molecular diagnostic test to the suite of tests you perform.

**How your data is used**
Using the information you supply, McKesson assigns a unique Z-Code™ Identifier to the test. Paramount will determine coverage for the Z-Code using our evidence-based medical policies. This determination will then be visible in the Diagnostics Exchange. While the information you share will be used by Paramount, you can also choose to share your data with other payers, or as part of other national initiatives, like CMS’ Molecular Diagnostics Services Program, MolDX. In Diagnostics Exchange, you will see what information is considered part of the public registry and what is designated as private.

**Getting started: Entering your laboratory and your genetic and molecular diagnostic testing data into the database**
Whether you are new to the Diagnostics Exchange, or have previously entered tests you perform into the database for other payers, the above table shows the steps you will need to take and the timeframe required. We recognize that our requirement to enter your genetic testing information will take staff time and we appreciate your team’s efforts. We want this process to be as smooth and efficient as possible and will work with your laboratory to help you with the tool and to answer any questions you may have.

**If you are new to the Diagnostics Exchange**
Servicing laboratories should take these steps by the dates indicated above. The tool is available on February 1, 2016, so you can begin registering and entering information at that time.

Register your laboratory with the Diagnostics Exchange. Go to: [https://app.mckessondex.com/login](https://app.mckessondex.com/login)
McKesson will process your registration in approximately one week. You’ll get an email with a username and temporary password, plus instructions for adding tests.

**Information about Training Opportunities**
To help you learn to use the DEX tool and develop efficient workflows, we offer the following resources:
- Sign up to participate in a training webinar by visiting INSERT URL. Training sessions will take place at the following dates/times:
  - February 17, 2016, 3-4 pm EST
  - February 23, 2016, 8-9 am EST
  - March 2, 2016, 12-1 pm EST
  - March 17, 2016, 3-4 pm EST
- Visit the below sites for training presentations:
  - How to Register Your Laboratory: [https://app.brainshark.com/mckessonhealth/thediagnosticsexchange](https://app.brainshark.com/mckessonhealth/thediagnosticsexchange)
  - How To Add Tests: [https://app.brainshark.com/mckessonhealth/addtest](https://app.brainshark.com/mckessonhealth/addtest)

If you have any difficulty registering for, or adding tests to, Diagnostics Exchange, please email DEX.Customer.Service@McKesson.com.

**Questions**
If you have questions, please call Network Management/Contract Manager, Tracy Finger at 419-887-2877 or 1(800)891-2542. As always, thank you for the care you provide to our members.