DEX® General FAQs

Program Overview

1. What is the DEX® Diagnostics Exchange Registry?

DEX is a web-based application designed to identify tests and help establish transparency between providers and payers. This tool enables labs to confidentially share test information with participating payers online. Labs register as an entity on the platform and submit their tests to obtain Z-Codes. Please visit the DEX Diagnostics Exchange Registry to login and use the platform.

2. What is the purpose of the DEX Z-Code®?

The Z-Code is a unique identifier that clearly identifies the test being performed on a claim, allowing the payer to know exactly what service was rendered. Providing the Z-Code on a claim, with the appropriate Recommended CPT® Code, may reduce the administrative burden labs may encounter surrounding billing for these services as it provides a means for the payer to automate adjudication or pre-authorization of claims. The Z-Code allows the payer to reproducibly and reliably assess medical necessity based on registered test information (such as intended use, methodology, and performance).

3. Which payers are participating with DEX and require a DEX Z-Code®?

- Medicare contractors (MACs) participating in the MolDX® Program:
    - **JM** A/B (N.C., S.C., Va., W.Va.) and **JJ** A/B (Tenn., Ga., Ala.) administered by Palmetto GBA.
    - **JE** A/B (American Samoa, Calif., Guam, Hawaii, Nev., North Marina Islands) and **JF** A/B (Alaska, Ariz., Idaho, Mont., N.D., Ore., S.D., Utah, Wash., Wyo.) administered by Noridian Healthcare Solutions.
    - **J5** A/B (Iowa, Mo., Kan., Neb.) and **J8** A/B (Mich., Ind.) administered by WPS Government Health Administrators.
    - **J15** A/B (Ky., Ohio) administered by CGS Administrators, LLC.
    - For more information and directions pertaining to the MolDX program, please visit their website at www.PalmettoGBA.com/MolDX.
- Participating payers will direct you to register in DEX and obtain Z-Codes if and when required. Current participating programs:
    - UnitedHealthcare® (Medicare Advantage and Commercial)
    - Optum Care (Medicare Advantage)

Other payers participating with DEX (requirements may vary):

- Medical Mutual of Ohio
- Fallon Health
- Blue Cross® and Blue Shield® of North Carolina

4. Which molecular diagnostics tests/CPT® codes are within scope for obtaining a DEX Z-Code?

Please review applicable payer policies for specific CPT® codes. **Z-Code requirements may vary by payer.**

See ***Test Submission Requirements*** for more information about FDA-approved/cleared tests.

Test Group Options	CPT® Code Range (subject to change)
Molecular	
MoPath Tier 1	81105-81112, 81120, 81121, 81161-81364, 81374, 81377, 81381, 81383
MoPath Tier 2	81400-81408
Genomic Sequencing Procedures	81410-81471, 81493
Unlisted	81479, 81599
MAAA codes	81504-81595, 0004M-0013M, 0016M, 0017M (DNA, RNA based molecular codes only)
PLA codes	Molecular codes only
Microbiology Procedure *(DNA, RNA-based tests only)*	
Infectious Disease	81513, 81514, 87154, 87483, 87505-87507, 87631-87633, 87636, 87637
Unlisted	87999

Other	87800, 87801
Proteomics *(as defined by MolDX in A59636)*	
Unlisted	81599
MAAA codes	81490, 81500, 81503, 81517, 81539
PLA codes	Select codes which include algorithmic analysis

Registration Topics

1. How does a lab register in DEX® to obtain Z-Codes®?

Visit the DEX Diagnostics Exchange Registry and select 'Register as a Lab or Hospital' on the log in page. Complete the registration form to gain access to the DEX Registry. If you receive a notification that your organization's NPI# or CLIA# is already registered, please contact us at DEX.Customer.Service@PalmettoGBA.com for assistance.

2. How many users can register per organization?

An organization can have two (2) registered users. A registered user for an organization gets a username that is specific to the contact person designated by each laboratory. Please do not forward or share this information. Other colleagues within your organization who want to register, may apply for a public user account. A public user account allows viewing of public information, which does not include Z-Codes.

3. Are DEX Z-Codes visible if I register as a public user?

DEX Z-Codes are not publicly visible. Public users may register in DEX and view test details that are publicly available which may include coverage and price information assessed by the MolDX® Program.

4. What lab test information submitted will be made available to public users in the DEX Diagnostics Exchange Registry?

The following fields are visible to public users of the DEX Registry: test name, lab test ID, lab/manufacturer name, lab test description, FDA 510(k)/PMA status and associated FDA document number, handling instructions, turnaround time, specimen information, patient instructions, MolDX Price, and MolDX Coverage determination. DEX Z-Codes are *not* publicly available.

As an administrator in the DEX Registry, you will be able to control privacy for other fields for your tests under your Organization's Test Privacy settings.

5. What if I do not perform the test, but I need the Z-Code from my reference lab for billing purposes?

Both the performing lab and client lab must register as an organization in DEX Registry. Only the performing lab needs to add the test to obtain a Z-Code. The client lab will need an approved Sharing request from the reference lab to obtain the Z-Code for the send out test(s). More information on using the Sharing feature can be found in the DEX Administrator FAQs (PDF).

Test Submission Requirements

1. Once registered as a user, how do I add my tests to the registry?

Select the 'Add Test' action button from the Catalog Overview or My Diagnostics Exchange tabs within DEX®. Complete all required fields and submit for review. For more information, see the DEX Diagnostics Exchange Help Files.

2. How can I reduce delays in obtaining a Z-Code®?

When adding a test, use the tooltip buttons to identify required information and view helpful hints. For example, the Test Description should succinctly describe the test's intended use, indications for ordering, and limitations. PGx tests should include the intended drug(s) of interest in the description.

DEX® General FAQs

3. If multiple tests may be performed and billed within one assay, is the lab required to separately register each test within the assay?

A DEX Z-Code identifier application is required for a single assay that may involve multiple tests in order to produce a single result. Ensure you enter your test as it is orderable to providers on your test requisition. A DEX Z-Code is assigned to individual orderable tests and/or panels and not to CPT® codes.

4. If a lab performs the same exact test in two different locations, operating under two different CLIA numbers, will the lab be required to submit both tests for unique identifiers?

If the test process is standardized and the same method is used to acquire results in both locations, the lab will only have to submit one application for the test. However, if there is a difference in the method, a separate application will be required for both locations.

5. If my lab makes changes to a test after a Z-Code is assigned, should I apply for a new Z-Code?

It is not necessary to apply for a new Z-Code when you make changes to a test. Please log into DEX and update the existing test record with the new information. If the changes are significant enough to constitute a new test, such as a methodology change or additional specimen types, a new Z-Code may be assigned.

6. Our lab no longer performs a test, should I retire it in the DEX Registry?

Yes, in the event a test is retired, please update your DEX test submission to reflect this change. The DEX Registry relies on accurate data entry and maintenance. Please review the DEX Administrator FAQs (PDF) for specific instructions.

7. Are labs required to register tests that use a code in the molecular diagnostics (MDx) code range and a code that is not listed in the MDx range of codes?

Yes, labs must register tests that include MDx and non-MDx range of codes in the test panel.

8. Is a Z-Code required for FDA-approved/cleared tests or modified FDA-approved/cleared kits?

Yes, a Z-Code is required in both scenarios* but the process may differ for obtaining the Z-Code (see #9). The FDA approval and clearance processes ensure only the clinical and analytical validity of the test. The FDA does not include clinical utility in their review, which is required for a technical assessment.

*NOTE: At this time, molecular syndromic panels for infectious disease pathogen identification that are FDA-approved/cleared do not require a Z-Code unless the panel meets any of the criteria below:

- If the FDA-approved/cleared test is being used outside of its intended use labeling (i.e., it is modified in any way) it requires a Z-Code.
- If no specific CPT® or PLA code exists for the panel, it will be billed with CPT® code 87999. Molecular tests using CPT® code 87999 requires a Z-Code, regardless of FDA-approval/clearance status.
- If you perform multiple (>1) FDA-approved/cleared molecular infectious disease pathogen identification tests on the same date of service (DOS), for the same intended use on the same patient sample, it is considered one distinct service and requires a Z-Code.

Refer to the Molecular Syndromic Panels for Infectious Disease FAQs (PDF) for more information.

9. Should the manufacturer or the performing lab add an unmodified FDA-approved/cleared in vitro diagnostic test kit to the DEX Registry?

If the test is within scope of the program requirements, then both the manufacturer and the performing lab should register their organization in DEX. The manufacturer should follow the steps to add the test and obtain the Z-Code. Once that is complete, the performing lab can obtain the Z-Code through the Sharing function within the DEX Registry.

If a performing lab *modifies* an FDA-approved/cleared test in any way from its intended use labeling, the resulting test is considered a LDT (laboratory developed test) and the performing lab will need to add the test to the DEX Registry themselves.

10. How do I obtain a DEX Z-Code for an unmodified FDA-approved/cleared test my lab is performing?

The Z-Code can be obtained through the *Sharing* functionality in DEX if the following conditions are met:

- The test is within scope of the program requirements.
- The test performed is FDA-approved/cleared and unmodified. *Note: If the test is being used in ways not consistent with its intended use labeling, then it is considered modified, and Sharing cannot be used.*
- The manufacturer of the test has registered in DEX and received a Z-Code.
- Your organization is registered in DEX.

If these conditions are met, then you can Request Sharing with the manufacturer in the DEX Registry and access the DEX Z-Code.

If the manufacturer has not registered or added the test and therefore you are unable to use the Sharing function, then your organization may need to add the test. Contact us for assistance.

11. If the kit used in a LDT is not FDA-approved/cleared, should the lab apply for a Z-Code for that kit?

Yes, an application for a Z-Code identifier will be required if the test has a CPT® code within scope for requiring a DEX Z-Code.

12. If a test is pending FDA-approval/clearance, should the laboratory provide the pending number in the submission?

We recommend the laboratory wait until the FDA determination is complete to add that information to your test in DEX.

13. How is algorithm defined in the test review?

An algorithm may be considered a meaningful and independent component of a laboratory process when ALL the following conditions are met:

- It is an unambiguous problem-solving operation that includes deploying a set of rules or calculations requiring computer processing;
- The test result (or a component of the result) is the calculated output of this process, and not an intermediary process;
- The same or similar test result could not be obtained without the use of this process;
- The input for the computation is derived from biological samples using analytical processes, and must include data from the sample submitted for the test;
- The process must:

- Either be required for the analytical result, OR
- If adjunct to the analytical result as a post-analytical process, the calculation itself must be independently found to be reasonable and necessary apart from the other components of the test.

Technical Assessment (TA) Evaluation

1. How will I know if my test needs additional Technical Assessment (TA) documentation?

If additional documents are needed for the TA, you will be notified by email. Once notified, please submit all completed documentation within 15 calendar days. In general, additional documentation is needed for more complex testing. For example, NGS-based tests require additional documentation and form submission.

2. Can I still submit Technical Assessment (TA) documentation if I miss the submission deadline?

We recommend completing all aspects of test validation prior to registering for a Z-Code® to prevent delays. If the 15-day deadline is missed, your test will not have demonstrated compliance with relevant standards and by default will be considered Not Successful. However, you may submit your technical assessment documentation at any time after the deadline for review.

3. Where should I send the requested Technical Assessment (TA) documentation?

Please refer to the Technical Assessment page for information on where to submit requested TA documents.

4. Why was my Technical Assessment (TA) Result updated to Not Successful?

Tests will be updated with a TA Result of Not Successful for the following reasons:

- The TA documentation submitted does not demonstrate analytical validity, clinical validity, and/or clinical utility per established TA evaluation procedures.
- The requested TA documentation was not received.
- The type of service submitted has not been established to have medical necessity.

For billing/claims related inquiries, please contact the participating payer.

Claims Related

1. I received email notification with assigned DEX Z-Codes® for my tests, when can I put them on a claim?

After DEX® assigns a Z-Code for a specific test, a Technical Assessment (TA) may be performed, and a result determined at the completion of the assessment. The Z-Code is effective and can be submitted on claims once the test has been assigned a TA result or has been assigned a recommended CPT® code.

- For tests that do not require additional TA documentation, this is complete in approximately 3-4 weeks.
- For tests that have submitted additional TA documentation, this process can take up to 60 days.

3. When will my test be updated with a Technical Assessment (TA) result in the DEX Registry?

Once the TA review process is complete, you will receive an email notification and the TA evaluation result will be updated in the DEX Registry.

4. Who should I contact with claim issues related to a Z-Code?

DEX Customer Service is not able to address claims related questions. Please contact your payer directly for assistance.

Commercial Payer Programs

1. What is Palmetto GBA®'s role in commercial health plans' use of DEX Z-Codes®?

Palmetto GBA, LLC is the owner/licensor of the DEX® Diagnostics Exchange and DEX Diagnostics Exchange Registry software that includes the DEX Z-Codes and clinical content comprising information about laboratory tests for molecular diagnostics.

Palmetto GBA completes the Technical Assessment (TA) evaluation to determine if a test demonstrates clinical utility (CU) and meets analytical and clinical validity (AV/CV) criteria. Palmetto GBA does not provide coverage decisions for commercial health plans.

2. I was notified by a commercial payer that my test requires a Z-Code. Are Z-Codes required for tests if I am not in a MolDX® jurisdiction?

Yes, private commercial payers may also utilize the DEX Registry and related services, and you will be notified by your commercial payer with instructions if Z-Code requirements apply to your billed services.

The MolDX Program (Administered by Palmetto GBA) is a separate program specific to certain Medicare jurisdictions.

3. If labs are required to obtain Z-Codes for both Medicare and commercial health plans, how does the process differ if my lab already has an established Z-Code?

The same Z-Code can be used for both the Medicare and commercial health plans; however, the Technical Assessment (TA) result may differ.

If you previously registered in DEX and already have an active Z-Code for your test, then you do not need to add the test again. However, the test may now require additional TA documentation to be submitted for the Non-Medicare TA Evaluation. If the test has been identified by our system as requiring TA documentation for the Non-Medicare TA Evaluation, you will receive an email notification. If you have questions about whether you will be required to submit additional TA documentation for your test, please Contact Us.

4. What is the Technical Assessment (TA) result?

The TA result is the determination resulting from the test review process performed by Palmetto GBA. In order for a Technical Assessment (TA) result to be Successful, the test will need to demonstrate it meets analytical validity (AV), clinical validity (CV), and clinical utility (CU) as outlined in Palmetto GBA established procedure or policy (based on evidentiary review).

Palmetto GBA does not provide coverage decisions for commercial health plans and the Technical Assessment result does not infer coverage.

5. Will there be a separate Technical Assessment (TA) result for commercial payers versus Medicare?

Depending on the intended use of the test, more than one TA result may be rendered. If the use of the test does not differ in Medicare and Non-Medicare utilization, only a Medicare

Evaluation or MolDX® Program result will be seen (depending on jurisdiction). This does not imply the services are intended for Medicare payers but that the result for the Medicare and Non-Medicare TA is the same.

If the commercial TA procedure differs from Medicare based on the intended use of the test, a Non-Medicare TA Evaluation result may be populated for the test.

NOTE: Not all tests will have a Non-Medicare TA performed when the intended uses from Medicare and Non-Medicare are distinct because the service might not have an evaluation procedure in place yet. Non-Medicare TA relies on Palmetto GBA creating a process for performing such a test. If the test type is determined to be part of a future phased rollout, you will be notified on next steps for the TA process. Tests with a Non-Medicare TA result of 'N/A' may be part of these future phased rollouts.

6. Will I see commercial health plan's coverage decisions in DEX?

No, commercial health plans coverage determinations are not available in the DEX Registry at this time. However, the test may be updated with a Technical Assessment (TA) result completed by Palmetto GBA.

Any *Coverage* result displayed under the MolDX Program is relevant for Medicare services within MolDX jurisdictions only.

For coverage questions, please contact your payer directly.