MDX Hawai'i

MDX Hawai'i Laboratory Benefit Management

Program Administrative Protocol

This Laboratory Benefit Management Program Administrative Protocol applies to laboratory services for MDX Hawai'i Medicare Advantage members, effective January 1, 2020.

To help improve quality and support appropriate selection of outpatient laboratory services, we are excited to announce that MDX Hawai'i has collaborated with Beacon Laboratory Benefit Solutions, Inc. (BeaconLBS®) to launch this Laboratory Benefits Management Program. The collaboration will provide a critical tool to help improve the quality of lab testing and help ensure our members continue to have timely, cost-effective access to the care they need.

Administration of the Program
Beacon Laboratory Benefit Solutions, Inc.® (BeaconLBS) will administer the Laboratory Benefit Management Program on behalf of MDX Hawai'i. This Administrative Protocol will be posted on www.MDXHawaii.com under the Provider Portal.

Physician Decision Support®
As part of the Laboratory Benefit Management Program, ordering and rendering care providers will use BeaconLBS Physician Decision Support for laboratory services. Physician Decision Support technology can make it easier to choose the right tests and laboratories for members by using evidence-based guidelines and industry best practices. Order your laboratory services through BeaconLBS's Physician Decision Support or an ordering platform interfaced with BeaconLBS Physician Decision Support when ordering any of the Decision Support Tests. These tests are listed in this Administrative Protocol in the Decision Support Tests section below.

To access Physician Decision Support:

- Use the standalone Physician Decision Support application available to registered users at www.BeaconLBS.com
- Use an electronic medical record system interfaced with Physician Decision Support
- BeaconLBS Call Center support at 1-844-919-0799 will be available (Monday – Friday, 8 a.m. – 8 p.m. HST)

Physician Registration
Please register before January 1, 2020, by visiting BeaconLBS.com and selecting Physician Login. You must register with BeaconLBS to use the standalone Physician Decision Support application to complete Decision Support Test ordering, including those which require prior authorization. If you have already registered with BeaconLBS, then this step is complete. If you submit test orders through a laboratory ordering application interfaced with Physician Decision Support, then Registration through the Physician Decision Support is not necessary.

If your practice performs and bills for laboratory tests that are not Clinical Laboratory Improvement Amendments (CLIA)-waived, you must also register as a laboratory.

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Laboratory Registration
Please register by visiting BeaconLBS.com and selecting Login > Lab Login. You'll need your group National Provider Identifier (NPI) and Tax Identification number to complete registration. By registering with BeaconLBS, ordering providers can select your laboratory for managed laboratory benefit services including prior authorization (precertification) for Decision Support Tests through Physician Decision Support.

Laboratory registration includes the following:

- Document laboratory quality criteria
- Identify and map information for the Decision Support Tests you perform
- Prepare to submit laboratory test identifiers on claims

Laboratory Quality Criteria
If you perform and bill for any laboratory services, you must demonstrate the following:

- CLIA certification level, appropriate for the level of tests performed, following Centers for Medicare & Medicaid Services (CMS) guidelines
- Accreditation from the College of American Pathologists (CAP) or The Joint Commission for certain complex tests
- Secondary review for certain complex pathology tests
- Sub-specialist review for certain complex tests

Test Mapping
Test mapping is the process in which tests or panels available from your laboratory are entered into the Physician Decision Support application. Test mapping will require that you provide the following information:

- Test identifier, or code, that your lab uses to represent your test or panel
- Name of your test or panel
- List of all associated Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) codes, with the number of units billed for each CPT or HCPCS code
- Test Synonym (Optional) – You can enter alternate key words associated with your test. These will be searchable by ordering providers
- Long Test Description (Optional) – You can add additional key words that are searchable by ordering providers

BeaconLBS will provide the tool and data transmission instructions to submit the test mapping information.

If your laboratory updates its test compendium after submission to BeaconLBS – including any additions, deletions or modifications – you should provide updated information to BeaconLBS thirty (30) calendar days prior to publishing those updates to providers, or as reasonably requested by BeaconLBS.

Labs-of-Choice™
BeaconLBS Labs-of-Choice offer consistent clinical practices and cost efficiency. These laboratories, and other network laboratories that register and meet quality criteria for tests, can be selected for laboratory services using Physician Decision Support.

BeaconLBS Labs-of-Choice providers must meet the following quality criteria:

- CLIA certification level, appropriate for the level of tests performed, following CMS guidelines
- CAP or The Joint Commission accreditation for certain complex tests
- Secondary review for certain complex pathology tests
- Sub-specialist review for certain complex tests
- Capability to receive test orders and send test results electronically

Labs-of-Choice providers must sign a contract with BeaconLBS and have their MDX Hawai'i Agreement amended in order to participate as a BeaconLBS Labs-of-Choice provider for MDX Hawai'i.

To learn more about Lab-of-Choice providers, please visit BeaconLBS.com.

Claim Submission Process
Lab test services you bill for should be performed by you or your staff. Billing for laboratory tests performed by another care provider or laboratory should reflect Centers for Medicare & Medicaid Services (CMS) policies regarding referred laboratory testing. All claim submissions must include a CLIA number or CLIA Certificate of Waiver number. Laboratory claims should be sent to MDX Hawai'i for process. Please refer to the Provider Operations Manual for the billing process.

Laboratory claims must contain the following:

- Your laboratory's CLIA or CLIA Certificate of Waiver number. If you submit claims with a CLIA Certificate of Waiver number, the associated claim line should include the appropriate modifier to represent a CLIA-waived test
- The individual ordering provider's name and NPI number
- Your laboratory's unique test identifier

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Claim Submission Formats

A laboratory test identifier is an internal laboratory code used to identify a specific test or panel offered by a laboratory. Please use the following guidelines to submit test identifiers, and other submission elements, on all laboratory claims.

Claim Format and Elements	CLIA Number Location Options	Ordering Provider Name and NPI Number Location Options	Test Identifier Submission Options
CMS-1500 (formerly HCFA 1500)	Must be represented in field 23	Submit the ordering provider name and NPI number in fields 17 and 17b, respectively. ***Or for offices billing Place of Service 11:*** Submit the ordering provider name and NPI in fields 33 and 33a, respectively.	Each time a laboratory CPT code or HCPCS code is populated in **Item Number 24D,** your corresponding test identifier should be placed in the ***shaded section*** **of 24A through 24G.**
UB04 or CMS 1450	Not applicable for UB04 or CMS 1450 claims	Submit the ordering provider name and NPI number in field 76.	Each time a laboratory CPT code or HCPCS code is populated in **Field Location 44,** your corresponding test identifier should be placed in **Field Location 43.**
HIPAA 5010 837 ***Professional***	Submit CLIA in 2300 loop, REF segment, with REF01 = X4, and REF02 = CLIA Number	Submit Name and NPI in 2310A loop, NM1 segment, with NM103 = First name, NM104 = last name, and NM108 = NPI ***Or for offices billing Place of Service 11:*** Submit Name and NPI in 2010AA loop, NM1 segment, with NM103 = first name, NM 104 = last name, and NM109 = NPI number	Each time a laboratory CPT code or HCPCS code is populated in the 2400 loop, SV1 Segment, with SV101-2 = CPT/ HCPCS code, then submit your **Test Identifier** for that service in NTE line segment. Submit Test Identifier for each CPT/ HCPCS Code in 2400 loop, NTE segment, NTE01 = Add and NTE02 = Test Identifier. **Example:** Submission of one Laboratory Test Identifier (e.g., 002303) per procedure line: NTE *ADD*002303~

HIPAA 5010 837 *Institutional*	Not applicable for institutional claim	Submit Name and NPI in 2310A loop, NM1 segment, with NM103 = first name, NM104 = last name, and NM108 = NPI ***Or for offices billing Place of Service 11:*** Submit Name and NPI in 2010AA loop, NM1 segment, with NM103 = first name, NM 104 = last name, and NM109 = NPI number	Each time a laboratory CPT code or HCPCS code is populated in the 2400 loop, SV2 Segment, with SV202-2 = CPT/HCPCS code then submit your **Test Identifier** for that service in SV202-7 line segment. Submit Test Identifier for each CPT/ HCPS Code in 2400 loop, SV2 Segment with SV202- 7 = Test Identifier. **Example:** Submission of one laboratory test identifier (e.g., 002303) for CPT 81099 with a billed amount of $125.15 and a unit of service of 1: SV2*0300*HC:81099:::::002303*125.15*UN*1~

This information describes specific requirements intended to supplement, not replace, all requirements in the ANSI X12N implementation guides, which are available at x12.org or wpc-edi.com.

Quality Criteria

Care providers who perform and bill for laboratory services must meet the following quality criteria. Laboratory quality criteria will be confirmed through the laboratory registration process.

Care providers who do not meet all criteria for the tests performed and billed will not be reimbursed. Per your agreement with MDX Hawai'i, these services may not be billed to the member.

CLIA*:* You must meet CLIA requirements and place your laboratory's CLIA number on the claim for services performed and billed.

Accreditation: You must have CAP or The Joint Commission accreditation if you perform and bill for the following services:

- Surgical pathology
- Cytology (non-gynecological)
- Molecular or genetic tests (e.g., genetics, infectious disease)
- Flow cytometry
- Advanced complex chemistry, hematology and/or immunology procedures that require interpretation (e.g., electrophoresis, gas chromatography, mass spectrometry)

Sub-Specialty Certification: * If your laboratory performs and bills for the following services, you must have the following corresponding sub-specialty certification. Certification may include board eligibility or board certification.

Laboratory Testing Discipline	Sub-Specialty Certification
Bone marrow (smear, flow cytometry, cytogenetics)	Hematopathology
Chromosomal Analysis	Cytogenetics
Cytology (includes fine needle aspiration)	Cytopathology
General anatomic pathology	Anatomic pathology
Genetic counseling	Board-certified genetic counselors
HLA Testing	American Society for Histocompatibility and Immunogenetics (ASHI) Director
Malignant dermatopathology (excludes services associated with Mohs surgery)	Dermatopathology
Molecular/Genetics	Molecular pathology, certified geneticist, or ABMG certified director

***Secondary Complex Pathology Reviews:* *** If your laboratory performs and bills for pathology services, you must provide secondary complex pathology review per the following chart.

***** We recommend that care providers meet both the Sub-Specialty Certification and Secondary Complex Pathology Reviews requirements. However, if both requirements can't be met for dermatopathology, cytopathology or hematopathology services, we'll accept either requirement.

Secondary Complex Pathology Review Requirements

Area	Description	Quality Measure
Cytopathology	All new malignancies to include all fine needle aspirates and non-gynecologic cytology	Secondary review required unless the initial review was performed by a cytopathologist. Both reviews can be performed by a general anatomic pathologist.
Dermatopathology	New severely dysplastic nevi, melanomas, atypical spitz nevi, malignant skin appendageal tumors, atypical lymphoid infiltrates and soft tissue tumors diagnostic of sarcoma	Secondary review required unless the initial review was performed by a dermatopathologist. Initial review may be completed by a dermatologist or an anatomic pathologist; secondary review may be performed by a dermato- pathologist or anatomic pathologist.

All Other Pathology	***Breast:*** All new malignancies, atypical hyperplasia and in situ cases. ***Gastrointestinal:*** New endoscopic directed biopsies and/or anal biopsy diagnostic of carcinoma; colon biopsies that have high grade dysplasia in a setting of inflammatory bowel disease; upper endoscopy directed biopsies with high grade dysplasia of either the stomach or esophagus; and liver needle biopsies regarded as diagnostic of carcinoma. ***Gynecology:*** All new biopsies diagnostic of carcinoma to include vaginal and cervical biopsies, LEEP and cone biopsies, endocervical curettings and endometrial biopsies. ***Head, Neck and Oral:*** New biopsies diagnostic of in situ or invasive carcinoma of the mucosa, salivary gland, sinonasal tract to include inverted papillomas. ***Respiratory:*** New needle biopsies and endoscopic biopsies diagnostic of carcinoma. ***Uropathology:*** All new genital-urinary biopsies to include kidney needle core biopsies** with in situ or invasive carcinoma. ***Other:*** New miscellaneous biopsies (not encompassed in other categories) that are malignant or suspect cases (e.g., dysplastic nevi)	Secondary review required; both reviews can be performed by general anatomic pathologist.
Hematopathology	New tissue biopsies with lymphoma to include intranodal and extranodal	Secondary review required unless the initial review was performed by a hematopathologist. Both reviews can be performed by a general anatomic pathologist.
****It is recommended that biopsies within certain specialized areas (e.g., non-tumor kidney biopsies, ophthalmological biopsies or brain biopsies) be reviewed by pathologists with advanced training.**		

Administrative Policies and Prior Authorization Requirements

Advance Notification

Advance Notification is required for Decision Support Tests rendered in the office (place of service 11), clinical laboratory (place of service 81), or outpatient hospital (place of service 19 or 22). Advance Notification is completed in full by the ordering provider using Physician Decision Support to place the order for laboratory tests. If Physician Decision Support is not used to order Decision Support Tests, the test will not be eligible for payment to the rendering laboratory.

Advance Notification is an administrative requirement, not a precertification, prior authorization or medical necessity determination.

The rendering laboratory will receive Advance Notification confirmation in the Outcome Summary form or available through the Laboratory PDS Portal at BeaconLBS.com. The Outcome Summary is a printable onscreen message that includes test ordering alerts and quality review results when a Decision Support Test is ordered through:

- Standalone Physician Decision Support application available to registered users at BeaconLBS.com
- An electronic medical record system interfaced with Physician Decision Support
- BeaconLBS Call Center Support will be available at 1-844-919-0799 (Monday – Friday, 8 a.m. – 8 p.m. HST)

If the rendering laboratory confirms that Advance Notification is not on file, the rendering laboratory should contact the ordering care provider to use the Physician Decision Support to place the order for laboratory services. Laboratory order through Physician Decision Support must be completed within 10 calendar days from the date of service. The date of specimen collection is the date of service.

Advance Notification is valid for 60 calendar days from the date of test order. If the date of service exceeds 60 calendar days, a new laboratory order through Physician Decision Support must be placed.

Some tests requiring Advance Notification may include validating the following requirements:

- **Ordering providers:** Completion of an electronic question and answer (Q&A) within Physician Decision Support which supports recommended evidence-based guidelines
- **Rendering providers:** CAP or Joint Commission accreditation, sub-specialty certification and/or secondary pathology review

The list of Decision Support Tests is included in this Administrative Protocol.

Prior Authorization (Precertification)

For any tests requiring Prior Authorization, ordering care providers should use Physician Decision Support to request Prior Authorization before ordering the service. Physician Decision Support will send the information to MDX Hawai'i and MDX Hawai'i will review the clinical information, make a determination and communicate the decision via MDX Hawai'i current processes. MDX Hawai'i clinical policies are available to physicians on the Provider Portal. Note: BeaconLBS does not authorize or deny coverage for services.

Ordering care providers can request a Prior Authorization via the following:

- Standalone Physician Decision Support application available to registered users at BeaconLBS.com.
- Use an electronic medical record system interfaced with Physician Decision Support
- BeaconLBS Call Center Support will be available at 1-844-919-0799 (Monday – Friday, 8 a.m. – 8 p.m. HST).

The rendering laboratory may access confirmation of the Prior Authorization in the Outcome Summary accompanying a lab order or at BeaconLBS.com. If the rendering laboratory confirms that Prior Authorization has not been requested, the rendering laboratory should contact the ordering provider to complete the Prior Authorization process.

No updates can be made to an existing Prior Authorization after the service has been delivered.

Decision Support Tests

Decision Support Tests are subject to separate requirements outlined in the previous sections of this Administrative Protocol. All Decision Support Tests either require Prior Authorization (Precertification) or Advance Notification by ordering using Physician Decision Support.

The following chart outlines the Prior Authorization (Precertification) requirements and Advanced Notification requirements by Decision Support Test.

TESTS REQUIRING PRIOR AUTHORIZATION (PRECERTIFICATION)				
Decision Support Test	**Electronic Q&A**	**CAP or Joint Commission Accreditation**	**Sub-specialty Certification**	**Secondary Pathology Review**
4K Score		Yes	Yes; certified molecular geneticist pathologist or ABMG-certified director	
Afirma™ Assay by Veracyte	Yes	Yes	Yes; certified molecular geneticist pathologist or ABMG-certified director	
Breast Cancer Index	Yes	Yes	Yes; certified molecular geneticist pathologist or ABMG-certified director	
Clonoseq	Yes	Yes	Yes; certified molecular geneticist pathologist or ABMG-certified director	
ConfirmMDx Epigenetic Molecular Assay	Yes	Yes	Yes; certified molecular geneticist pathologist or ABMG-certified director	
CYP2C19 gene	Yes	Yes	Yes; certified molecular geneticist pathologist or ABMG-certified director	
EndoPredict Breast Cancer Test	Yes	Yes	Yes; certified molecular geneticist pathologist or ABMG-certified director	
GeneSight® Psychotropic	Yes	Yes	Yes; certified molecular geneticist pathologist or ABMG-certified director	
Guardant360® Plasma-Based Comprehensive Genomic Profiling in Non-Small Cell Lung Cancer (NSCLC)	Yes	Yes	Yes; certified molecular geneticist pathologist or ABMG-certified director	
Hereditary Breast and Ovarian Cancer Testing (BRCA 1/2) and Multi-Gene BRCA	Yes	Yes	Yes; certified molecular geneticist pathologist or ABMG-certified director	
HLA-B*15:02 Genetic Testing	Yes	Yes		
IHC and Special Stains	Yes	Yes		
MammaPrint Breast Cancer Recurrence Assay		Yes	Yes; certified molecular geneticist pathologist or ABMG-certified director	
Molecular Gene, Statutory Exclusion (singe gene & panels)	Yes	Yes	Yes; certified molecular geneticist pathologist or ABMG-certified director	
Multi-Gene Pharmacogenetic Testing	Yes	Yes	Yes; certified molecular geneticist pathologist or ABMG-certified director	

Oncotype DX Breast Cancer Test	Yes	Yes	Yes; certified molecular geneticist pathologist or ABMG-certified director	
Procalcitonin (PCT)	Yes			
Progensa® PCA3 Assay	Yes	Yes	Yes; certified molecular geneticist pathologist or ABMG-certified director	
Prosigna Breast Cancer Assay	Yes	Yes	Yes; certified molecular geneticist pathologist or ABMG-certified director	
Tumor Profiling Panels	Yes	Yes	Yes; certified molecular geneticist pathologist or ABMG-certified director	

TESTS REQUIRING ADVANCED NOTIFICATION*				
Decision Support Test	**Electronic Q&A**	**CAP or Joint Commission Accreditation**	**Sub-specialty Certification**	**Secondary Pathology Review**
Chlamydia/ Gonococcus, NAT	Yes	Yes		
Cytology (Non-Gynecological)		Yes	Yes; cytopathologist	Yes
Drug Testing - Definitive and Presumptive	Yes	Yes		
Human Immunodeficiency Virus 1 (HIV-1), Quantitative, RNA	Yes	Yes		
Human Papillomavirus (HPV), High-risk DNA Detection	Yes	Yes		
Leukemia/ Lymphoma Immunophenotyping Profile (by flow Cytometry)		Yes		
Pathology - All Other		Yes		Yes
Pathology - Dermatopathology		Yes	Yes; dermatopathologist	Yes
Pathology - Hematopathology		Yes	Yes; hematopathologist	Yes
Prostate Specific Antigen (PSA)	Yes			
Parathyroid hormone (PTH)	Yes			
Testosterone	Yes			
Thyroid Testing Including: Thyroid Panel;	Yes (No for TSH)			

Thyroxine (T4), Free; Triiodothyronine (T3), Free; Thyroid Stimulating Hormone (TSH)				
UroVysion	Yes	Yes		
Vaginitis/ Vaginosis	Yes	Yes		
Vitamin B12	Yes			
Vitamin D, 25-Hydroxy	Yes			

*Advanced Notification means placing order through Physician Decision Support

For More Information

Resource	Where To Go	What You Can Do There
MDX Hawai'i	**Online:** www. MDXHawaii.com **Phone:** Please refer to the phone number on the member ID card.	• Learn more about the Laboratory Benefit Management Program at www.MDXHawaii.com • Verify claim payment status and submit a claim appeal for certain outpatient laboratory test services as described in the Advance Notification and Prior Authorization Requirements section of this administrative protocol.
BeaconLBS	**Online:** BeaconLBS.com **Phone:** Call BeaconLBS Call Center at 1-844-919-0799. (Available Monday – Friday, 8 a.m. to 8 p.m. HST) **Email:** AskBeacon@beaconlbs.com or LabSupport@beaconlbs.com (for labs only)	• View program information. • Register for the Laboratory Benefit Management Program. • Request participation in the Laboratory of Choice network, if interested. If you're already a Laboratory of Choice provider, contact BeaconLBS for questions about your contract, including reimbursement. • Access the standalone Physician Decision Support tool and technical support.