MEDICAL POLICY	Prostate: Protein Biomarkers and Genetic Testing (Medicare Only)
Effective Date: 9/1/2022	Medical Policy Number: 95
 9/1/2022	Medical Policy Committee Approved Date: 10/16; 12/17; 1/18; 3/18; 8/18; 8/19; 9/19; 11/19; 2/2020; 3/2021; 3/2022; 8/2022
Medical Officer Date	

See Policy CPT CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

Medicare Only

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

Service	Code(s)	Medicare Guidelines
4Kscore Assay (developed by OPKO, marketed by BioReference Laboratory; New Jersey)	CPT 81539	Select the applicable LCD based on testing location: • Testing performed in the states of NC, SC, AL, GA, TN, VA, WV: LCD: MolDX: 4Kscore Assay (L36763) • Testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY: MolDX: 4Kscore Assay (L37122) • Testing performed in the states of CA, HI or NV: MolDX: 4Kscore Assay (L37120) • Testing performed in the states of IL, MN, WI, CT, NY, ME, MA, NH, RI, VT: Biomarker Testing (Prior to Initial Biopsy) for Prostate Cancer Diagnosis (L37733)

		• Testing performed in the states of NJ, CO, NM, OK, TX, AK, LA, MS, DE, MD, PA: 4Kscore Test Algorithm (L37792) • Testing performed in the state of FL: LCD: 4Kscore Test Algorithm (L37798) • Testing performed in the states of KY or OH: LCD: MolDX: 4Kscore Assay (L36979) Testing performed in the states of IA, KS, MO, NE, IN, MI: LCD: MolDX: 4Kscore Assay (L37013)
Decipher® Prostate Cancer Classifier Assay (Decipher Biosciences; California) *Oncotype DX® Genomic Prostate Score Assay (California)* *Prolaris® Prostate Cancer Genomic Assay (Utah)*	Varies, but includes CPT 81479, 81541, 81542, or 0047U	For the **Decipher® Prostate Cancer Classifier and Oncotype DX® Genomic Prostate Score Assays**: • Apply the LCD for MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease (L38339) For the **Prolaris Prostate Cancer Genomic Assay**: • Apply the LCD for MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease (L38341) **NOTE:** While the LCDs above specifically call out the *Decipher* test by name, they also state **other genomic tests may be eligible for coverage as well** if evaluated by the MolDX Program Contractor via the technical assessment (TA) process. Both the ***Oncotype DX® Genomic Prostate Score Assay*** and the ***Prolaris*** test by Myriad Genetics have completed this requirement and are listed as 'covered' tests in the DEX Exchange registry. Thus, the criteria from the above LCDs also apply to these tests as indicated.
ConfirmMDx Epigenetic Molecular Assay (MDxHealth; Irvine, California)	CPT 81479, 81551	Apply the LCD for MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L39005) *(This test is listed as a potentially covered test in the companion LCA A58718 when the member meets the rest of the LCD criteria.)*
PCA3 Testing *Includes the Progensa® PCA3 Assay (MetaMark Genetics; Massachusetts or Georgia)*	81313	For PCA3 testing that is specifically the Pregensa® test, apply the following: • Testing performed in the states of VA, WV, NC, SC, GA, TN, AL: LCD for MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L38985) *(Use this coverage criteria for testing performed in either location. This test is listed as a potentially covered test in the companion*

		LCA A58724 when the member meets the rest of the LCD criteria.) For PCA3 testing in general that is **not** specifically the Pregensa® test, apply the following: • Testing performed in the states of IL, MN, WI, CT, NY, ME, MA, NH, RI, VT: LCD for Molecular Pathology Procedures (L35000) *(See criteria for PCA3 testing within the LCD, which is the same criteria for CPT 81313 in LCA A56199)* • Testing performed in AK, ID, OR, WA, UT, AZ, MT, ND, SD, and WY: LCD for MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L39007) Testing performed in CA and NV: LCD for MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L39005)
Oncotype DX® AR-V7 Nucleus Detect Test (California)	81479	LCD: MolDX: Phenotypic Biomarker Detection from Circulating Tumor Cells (L38643) (The LCD requires successful completion of TA review of the test; this test meets this LCD requirement.)
ProMark Risk Score (MetaMark Genetics; Massachusetts or Georgia)	CPT 81479	LCD: MolDX: ProMark Risk Score (L36665) *(Use this LCD for testing performed in either location)*
ExoDx prostate (also known as ExosomeDx®, EPI, or IntelliScore) (Exosome Diagnostics; Massachusetts) (CPT 0005U) *Prostate Health Index (PHI or phi) (Beckman Coulter)*	Varies	LCD: Biomarker Testing (Prior to Initial Biopsy) for Prostate Cancer Diagnosis (L37733)
UroSeq® Hereditary DNA Repair Panel (Theranostix, Inc. D/B/A Strand Diagnostics; Indiana)		LCD: MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer (L38972) *(The LCD requires successful completion of TA review of the test; this test meets this LCD requirement.)* **NOTE:** While the UroSeq® test may be eligible for coverage, the *know error®* system for specimen validity that may also be performed with the UroSeq® is **not** considered medically necessary according to LCA

		A55172, even if requested in connection to the UroSeq® test. Separate coverage or reimbursement will not be allowed for the *know error®* system.
RNAinsight™ for ProstateNext® (Ambry Genetics; California) (CPT 0133U) *SelectMDx (MDxHealth; California) (CPT 81479)* *NeoLAB Prostate Liquid Biopsy (NeoGenomics Laboratories, Inc.; California) (CPT 0011M)* *Apifiny® Score (Armune BioScience, Inc.; Michigan) (CPT 0021U)* *Mi-Prostate score (also known as Michigan Prostate Score or MIPS) (MLabs; Michigan) (CPT 0113U)* *Prostate Cancer Risk Panel (CPT 0053U) (Mayo Clinic, Mayo Medical Laboratories, headquartered in Minnesota)* *EpiScore*	Varies	These tests are considered **not medically necessary**, based on Medicare guidelines. *See "Policy Guidelines" below.*

POLICY GUIDELINES

Diagnostic Laboratory Test Jurisdiction

The Company policy *PHA Medicare Medical Policy Development and Application* (MP# 50) describes the Plan's hierarchy with respect to Medicare medical policy development. In compliance with Medicare guidelines, some LCDs and LCAs used may be for test service areas **outside** of the Company service area.

This is because Medicare's general rule regarding jurisdiction of claims furnished by an independent laboratory is that jurisdiction lies with the A/B MAC (B) (aka, Medicare Contractor) serving the **area in which the laboratory test is performed**.[1]

However, there may be exceptions to this rule. According to Medicare, while jurisdiction for laboratory services normally lies with the carrier serving the performing laboratory service area, there are situations where a regional or national lab chain jurisdiction (e.g., Quest Diagnostics, LabCorp, etc.) lies with a single carrier.[8] Therefore, tests performed by a national laboratory chain may have a single carrier established within the Company medical policies for all laboratory services they perform, regardless of the individual laboratory location. This allows for consistent outcomes for all members who receive the same test by the same lab chain.

Another exception to this rule involves "referring laboratory tests." This is when one laboratory sends the sample to another laboratory for processing. Under Medicare rules for referred tests, the location of the billing provider determines jurisdiction for claim payment and coverage criteria. Note that also under Medicare rules, only one laboratory is allowed to bill for the services rendered. If the performing laboratory and billing provider both submit a claim, then the performing laboratory's claim is the claim that would adjudicate according to member benefit.[10-12]

Medicare's Molecular Diagnostic (MolDX) Program Contractor

While many Medicare contractors (MACs) have adopted guidelines developed and published by the Molecular Diagnostic Services (MolDX) Program for their service areas, the program is **not** national in scope. MolDX-related reference materials only apply to genetic and molecular tests performed in the following states: OR, WA, AK, ID, UT, AZ, MT, ND, SD, WY, CA, NV, HI, NC, SC, AL, GA, TN, VA, WV, KY, OH, IA, KS, MO, NE, IN, and MI.[3]

The MolDX Program was developed by Palmetto GBA in 2011. The MolDX Contractor performs the following functions[3,4]:

- Establish clinical utility expectations.
- Complete technical assessments of published test data to determine clinical utility and coverage of individual tests.
- Develop unique test identifiers (Z-codes), adding to the DEX™ register of molecular diagnostic tests to allow for automated claims processing and to track utilization.
- Establish reimbursement.

Table 1

Genetic tests performed within a MolDX service area are required to undergo a technical assessment (TA) review by MolDX. The LCDs in Table 1 detail this requirement:

	LOCATION/MEDICARE CONTRACTOR				
	NORIDIAN J-F	***NORIDIAN J-E***	***PALMETTO GBA J-J AND J-M***	***WPS J-5 AND J-8***	***CGS J-15***

	OR, WA, AK, ID, UT, AZ, MT, ND, SD, and WY	CA and NV	NC, SC, AL, GA, TN, VA, and WV	IA, KS, MO, NE, IN, and MI	KY and OH
General MolDX Requirements	L36256	L35160	L35025	L36807	L36021

The outcome of these TA reviews is maintained in the DEX™ Diagnostics Exchange registry catalog and when possible, the coverage outcome is included within this medical policy to assist with coverage decision-making.

- Tests listed as "not covered" in this catalog have had clinical utility and analytical validity (CU/AV) reviewed and were determined to be **not medically reasonable or necessary** for Medicare under *Social Security Act, §1862(a)(1)(A)*.
- Tests which have **not yet** completed the required TA review are by default also considered to be **not medically reasonable or necessary** for Medicare under *§1862(a)(1)(A)*, based on the requirements found in the LCDs noted in Table 1 above.
- Tests listed as "covered" in this catalog have completed the required TA review and have been determined to be **medically reasonable or necessary** for Medicare under *§1862(a)(1)(A)*; however, this coverage is not automatic, as both of the following must be met:
    - Applicable NCD, LCD, and LCA criteria are met; and,
    - The member has signs/symptoms of a relevant disease or condition.

If a test is not specifically called out in this medical policy, additional research is required to determine coverage.

Table 2: Tests relevant to this policy include the following

This list only applies to tests which do not have an LCD or LCA specific to that individual test in the Medicare guideline table above. This list was accurate at the time of publication, but it is subject to change at any time by the Medicare MolDX Program contractor. A "MolDX TA Review Outcome" of "Covered" does not indicate the test is automatically covered. All relevant criteria from the above Medicare references as applicable to the individual test must still be met.

Proprietary Test Name	Laboratory	MolDX TA Review Outcome (as found in the DEX™ Diagnostics Exchange registry catalog)
SelectMDx (CPT 81479)	MDxHealth; Irvine (California)	Not covered
NeoLAB Prostate Liquid Biopsy (CPT 0011M)	NeoGenomics Laboratories, Inc. (California)	Not covered

Apifiny® Score (CPT 0021U)	Armune BioScience, Inc. (Michigan)	Not covered *(No TA review performed as of most recent policy review date)*
Mi-Prostate score (also known as Michigan Prostate Score or MIPS) (CPT 0113U)	MLabs (Michigan)	Not covered
UroSeq® Hereditary DNA Repair Panel	Stand Diagnostics (Indiana)	Covered
Oncotype DX® AR-V7 Nucleus Detect Test	Exact Sciences (California)	Covered
Oncotype DX® Genomic Prostate Score Assay	Exact Sciences (California)	Covered
RNAinsight™ for ProstateNext® (CPT 0133U)	Ambry Genetics; California	Not covered

Test coverage or non-coverage positions included in this medical policy were accurate at the time of policy publication, but they are subject to change by the Medicare MolDX Program contractor at any time. Appeals to dispute non-coverage should include documentation by the MolDX Contractor which reflects a positive coverage decision (e.g., copy of the MolDX determination letter).

Non-MolDX Service Area Genetic Testing

Services areas which have **not** adopted MolDX guidelines include testing performed in the following states: FL, CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, PA, IL, MN, WI, CT, NY, ME, MA, NH, RI, and VT.

Table 3

The LCDs in Table 3 provide general coverage requirements for each jurisdiction area:

	LOCATION/MEDICARE CONTRACTOR		
STATE(S)	**MEDICARE CONTRACTOR**	**LCD**	**COVERAGE REQUIREMENTS**
IL, MN, WI, CT, NY, ME, MA, NH, RI, and VT	***National Government Services (NGS) J-6 and J-K***	L35000	This LCD requires clinical utility and analytical validity be established, but it doesn't address all tests by name specifically. For panels, this LCD also states, "testing would be covered ONLY for the number of genes or test that are reasonable and necessary to obtain necessary information for therapeutic decision making." In the absence of specific guidance in this LCD, the PHP Company policies for genetic tests provide a peer review of medical literature to evaluate clinical utility/analytical validity. When the biomarkers included in a test do not have proven clinical validity/utility, the test is not medically reasonable or necessary under *Social Security Act, §1862(a)(1)(A)* for Medicare members.

CO, NM, OK, TX, AR, LA, MI, DE, MD, NJ, and PA	***Novitas J-H and J-L***	L35062 / L35396	The LCD L35062 requires clinical utility and analytical validity be established, but it doesn't address all tests by name specifically. Additionally, for multi-biomarker panel test, the LCD L35396 requires evidence to support how "each requested biomarker can be individually contributory." In the absence of specific guidance in these LCDs, the PHP Company policies for genetic tests provide a peer review of medical literature to evaluate clinical utility/analytical validity. When the biomarkers included in a test do not have proven clinical validity/utility, the test is not medically reasonable or necessary under *Social Security Act, §1862(a)(1)(A)* for Medicare members.
FL	***First Coast Service Options J-N***	L34519	The LCD L34519 requires tests to undergo evaluation to establish clinical utility and analytical validity, based on published peer reviewed medical literature, or be FDA-approved, in order to be eligible for coverage. However, it doesn't address all tests by name specifically. For panels, this LCD also states, "testing would be covered ONLY for the number of genes or test that are reasonable and necessary to establish a diagnosis." In the absence of specific guidance in this LCD, the PHP Company policies for genetic tests provide a peer review of medical literature to evaluate clinical utility/analytical validity. When the biomarkers included in a test do not have proven clinical validity/utility, the test is not medically reasonable or necessary under *Social Security Act, §1862(a)(1)(A)* for Medicare members.

As noted in Table 3, all of the listed LCDs require tests undergo evaluation to establish clinical utility (CU) and analytical validity (AV) in order to be eligible for coverage. However, due to the large number of proprietary tests marketed and available, most genetic tests – particularly panel tests – are not specifically called out by name within an LCD or LCA, nor do LCDs or LCAs provide the outcome for the peer-reviewed CU/AV for most tests.

The Company policy *PHA Medicare Medical Policy Development and Application* (MP# 50) describes the Plan's hierarchy with respect to Medicare medical policy development. Medicare rules and regulations state that when no NCD, LCD, LCA, or other Medicare coverage guideline exists, Medicare allows Medicare Advantage Organizations (MAOs) to make coverage determinations based on an objective, evidenced-based process. Therefore, in the absence of a specific Medicare policy or reference for a test, Company Commercial medical policy criteria may be applied to panel tests which do not have clinical utility or analytical validity documented within an LCD directly. Tests which are considered "investigational" in a Company Commercial policy will be denied as not medically reasonable or necessary under *Social Security Act, §1862(a)(1)(A)* for Medicare members.

Table 4: Tests relevant to this policy include the following:

Note: This list was accurate at the time of publication, but it is subject to change at any time by a Medicare contractor.

Proprietary Test Name	Laboratory	Coverage/Non-coverage Outcome
Prostate Cancer Risk Panel (0053U)	Mayo Clinic, Mayo Medical Laboratories (Headquartered in Minnesota)	Not Covered
EpiScore		Not Covered

BILLING GUIDELINES

For applicable billing guidelines, please see related local coverage articles (LCAs):

- Local Coverage Article: Billing and Coding: MolDX: 4Kscore Assay (A57337)
- Local Coverage Article: Billing and Coding: MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease (A57236)
- Local Coverage Article: Billing and Coding: MolDX: ConfirmMDx Epigenetic Molecular Assay (A57606)
- Local Coverage Article: MolDX: Oncotype DX Genomic Prostate Score Coding and Billing Article (A56372)
- Local Coverage Article: Billing and Coding: MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease (A57236)
- Local Coverage Article: Progensa® PCA3 Assay Billing and Coding guidelines (A54492)
- Local Coverage Article: Billing and Coding: MolDX: ProMark Risk Score (A57609)

In accordance with the LCDs and LCAs listed above, CMS has indicated that a number of the assays addressed in the policy be billed with specific codes.

Assay	Code
4K score	81539
ConfirmMDx	81479, 81551
Decipher	81479
Oncotype	81479, 0047U
PCA3	81313
Prolaris	81479, 81541
ProMark	81479
NeoLAB™	0011M
Mi-Prostate Score (MiPS)	0113U
Apifiny®	0021U

ExosomeDx® Prostate (IntelliScore)	0005U
Prostate Cancer Risk Panel	0053U
RNAinsight™ for ProstateNext®	0133U

CPT CODES

Medicare Only	
Prior Authorization Required	
0005U	Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score
0047U	Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score
81313	PCA3/KLK3 (prostate cancer antigen 3 [non-protein coding]/kallikrein-related peptidase 3 [prostate specific antigen]) ratio (eg, prostate cancer)
81539	Oncology (high-grade prostate cancer), biochemical assay of four proteins (Total PSA, Free PSA, Intact PSA, and human kallikrein-2 [hK2]), utilizing plasma or serum, prognostic algorithm reported as a probability score
81541	Oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 46 genes (31 content and 15 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a disease-specific mortality risk score
81542	Oncology (prostate), mRNA, microarray gene expression profiling of 22 content genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as metastasis risk score
81551	Oncology (prostate), promoter methylation profiling by real-time PCR of 3 genes (GSTP1, APC, RASSF1), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a likelihood of prostate cancer detection on repeat biopsy
Not Covered Based on an LCD or LCA, all codes in this section are **non-covered** by Medicare.	
0011M	Oncology, prostate cancer, mRNA expression assay of 12 genes (10 content and 2 housekeeping), RT-PCR test utilizing blood plasma and/or urine, algorithms to predict high-grade prostate cancer risk
0021U	Oncology (prostate), detection of 8 autoantibodies (ARF 6, NKX3-1, 5'-UTR-BMI1, CEP 164, 3'-UTR-Ropporin, Desmocollin, AURKAIP-1, CSNK2A2),
0053U	Oncology (prostate cancer), FISH analysis of 4 genes (ASAP1, HDAC9, CHD1 and PTEN), needle biopsy specimen, algorithm reported as probability of higher tumor grade
0113U	Oncology (prostate), measurement of PCA3 and TMPRSS2-ERG in urine and PSA in serum following prostatic massage, by RNA amplification and fluorescence-based detection, algorithm reported as risk score

0133U	Hereditary prostate cancer–related disorders, targeted mRNA sequence analysis panel (11 genes) (List separately in addition to code for primary procedure)
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then **prior-authorization is required.**	
81479	Unlisted molecular pathology procedure
81599	Unlisted multianalyte assay with algorithmic analysis
84999	Unlisted chemistry code

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

REFERENCES

1. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, §50.5 - Jurisdiction of Laboratory Claims; Available at: https://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/downloads/clm104C16.pdf [Cited 09/02/2021]
2. Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, §13.5.4 - Reasonable and Necessary Provision in an LCD; Available at: https://www.cms.gov/Regulationsand-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf [Cited 09/02/2021]

3. Palmetto GBA MolDX Manual; Available at: https://www.palmettogba.com/Palmetto/moldx.Nsf/files/MolDX_Manual.pdf/$File/MolDX_Manual.pdf?Open& [Cited 09/29/2021]
4. Healthcare Fraud Prevention Partnership (HFPP) White Paper for Genetic Testing Fraud, Waste, and Abuse; Available at: https://www.cms.gov/hfpp/hfpp-white-papers [Cited 09/29/2021]
5. Noridian web page for Molecular Diagnostic Services (MolDX); Last Updated: 9/23/2021; Available at: https://med.noridianmedicare.com/web/jfb/policies/moldx
6. Medicare Managed Care Manual, Ch. 4 - Benefits and Beneficiary Protections, §90.4.1 - MACS with Exclusive Jurisdiction over a Medicare Item or Service; Available at:
7. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf
8. Medicare Claims Processing Manual, Chapter 1 - General Billing Requirements, §10.1.5.4 - Independent Laboratories; Available at: https://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/Downloads/clm104c01.pdf
9. Noridian LCA for Billing and Coding: MolDX: Targeted and Comprehensive Genomic Profile Next-Generation Sequencing Testing in Cancer (A56518); Available at: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=56518
10. Medicare Claims Processing Manual, Ch. 1 - General Billing Requirements, §10.1.5.4.1 – Cases Involving Referral Laboratory Services; Available at: https://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/Downloads/clm104c01.pdf
11. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, §40.1 – Laboratories Billing for Referred Tests; Available at: https://www.cms.gov/regulations-andguidance/guidance/manuals/downloads/clm104c16.pdf
12. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, §50.5.1 - Jurisdiction Of Referral Laboratory Services; Available at: https://www.cms.gov/regulations-andguidance/guidance/manuals/downloads/clm104c16.pdf