Concert Genetic Testing: ~~Lung Disorders~~Respiratory

Reference Number: LA.CP.CG.12
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Revision Log

Coding implications

See Important Reminder at the end of this policy for important regulatory and legal information.

OVERVIEW

~~One of the most common inherited lung disorders is alpha-1 antitrypsin deficiency (AATD). AATD is an autosomal recessive genetic disorder that results in decreased production of the alpha-1 antitrypsin (AAT) protein, or production of abnormal types of the protein that are functionally deficient. Individuals with AATD have an increased risk to develop lung and liver disease. Genetic testing to diagnose AATD aids in directing proper treatment and identifying at-risk family members.~~

~~With the use of donor-derived cell-free DNA (dd-cfDNA), biomarker tests have been developed as an alternative to more invasive procedures for post-lung transplant care to optimize graft longevity while avoiding side effects and toxicity of immunosuppressive therapies.~~

This policy addresses the use of diagnostic tests for disorders that affect the lungs.

For additional information see the Rationale section.

The tests, CPT codes, and ICD codes referenced in this policy are not comprehensive, and their inclusion does not represent a guarantee of coverage or non-coverage. Please see the Concert Platform for additional registered tests.

POLICY REFERENCE TABLE

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted ~~2023~~2024, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only and may not support medical necessity.

Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

NOTE: Coverage is subject to each requested code's inclusion on the corresponding LDH fee schedule. Non-covered codes are denoted (*) and are reviewed for Medical Necessity for members under 21 years of age on a per case basis. The non-covered codes will only be denoted in the table below and not throughout the policy. Please only reference the policy reference table for covered and non-covered codes.

The tests, ~~associated laboratories,~~ CPT codes, and ICD codes ~~contained within~~referenced in this ~~document serve only as examples to help users navigate claims and corresponding criteria; as such, they~~policy are not comprehensive, and ~~are~~their inclusion does not represent a guarantee of coverage or non-coverage. Please see the Concert Platform for ~~a comprehensive list of~~additional registered tests.

~~Criteria Sections~~ CRITERIA SECTIONS	~~Example Tests (Labs)~~EXAMPLE TESTS (LABS)	~~Common CPT Codes~~COMMON BILLING CODES	~~Common ICD Codes~~REF	~~Ref~~
~~Alpha-1 Antitrypsin Deficiency~~Alpha-1 Antitrypsin Deficiency				
~~*SERPINA1* Common Variant Analysis or Sequencing and/or Deletion/Duplication Analysis~~*SERPINA1* Common Variant Analysis or Sequencing and/or Deletion/Duplicati	Alpha-1 Antitrypsin (AAT) Mutation Analysis (Quest Diagnostics)	~~81332*~~	81332*, E88.01	~~1~~4	
	SERPINA1 Full Gene Sequencing and Deletion/Duplication (Invitae)		81479, E88.01		

on Analysis				
~~Donor-Derived Cell-free DNA for Lung Transplant Rejection~~Cystic Fibrosis				
~~Evidence-Based Donor-Derived Cell-free DNA for Lung Transplant Rejection~~Diagnostic *CFTR* Sequencing and/or Deletion/Duplication Analysis	~~Prospera Lung (Natera)~~Cystic Fibrosis Complete Rare Variant Analysis, Entire Gene Sequence (Quest Diagnostics)	~~81479~~81223, E84.0-9, P09, Q55.4, R94.8, Z13, Z31, Z34, Z82.79, Z83, Z84	~~T86.810, Z48.24, Z94.2~~1, 3	~~5~~
	~~AlloSure Lung (CareDx)~~Cystic Fibrosis Gene Deletion or Duplication (Quest Diagnostics)	81222, E84.0-9, P09, Q55.4, R94.8, Z13, Z31, Z34, Z82.79, Z83, Z84		
~~Emerging Evidence Donor-Derived Cell-free DNA for Lung Transplant Rejection~~ *CFTR* Intron 9 PolyT and TG Analysis (previously called Intron 8 polyT/TG)	~~Eurofins TRAC dd-cfDNA (Transplant Genomics Inc)~~ *CFTR* Intron 8 Poly-T Analysis (Quest Diagnostics)	~~0118U*~~81224*, E84.0-9, P09, Q55.4, R94.8, Z13, Z31, Z34, Z82.79, Z83, Z84	2	
~~Other Covered Lung Disorders~~Other Covered Lung Disorders				
~~Other Covered Lung Disorders~~Other Covered Lung Disorders	See list below	81400~~*~~*, 81401*, 81402*, 81403*, 81404*, 81405*, 81406*, 81407*, 81408*	5, 6, 7	~~2, 3, 4~~

~~OTHER~~ RELATED POLICIES

This policy document provides criteria for ~~Genetic Testing for Lung Disorders.~~testing related to respiratory disorders. Please refer to:

- ***~~Genetic~~Specialty* Testing: Multisystem *~~Inherited Disorders, Intellectual Disability, and Developmental Delay~~Genetic Conditions*** for criteria related to diagnostic ~~testing for cystic fibrosis~~tests for genetic disorders that affect multiple organ systems (e.g. whole exome and genome sequencing, chromosomal microarray, and ~~other multisystem inherited disorders.~~multigene panels for broad phenotypes).

- ***~~Genetic Testing:~~ General Approach to ~~Genetic and Molecular~~Laboratory Testing*** for ~~criteria~~ related to ~~genetic~~respiratory testing ~~for lung disorders and disease that are~~, including known familial variant testing, that is not specifically discussed in this or another non-general policy~~, including known familial variant testing.~~.

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CRITERIA

It is the policy of ~~health plans affiliated with Centene Corporation~~Louisiana Healthcare Connections® that the specific genetic testing noted below is **medically necessary** when meeting the related criteria:

~~ALPHA-1 ANTITRYPSIN DEFICIENCY~~

~~SERPINA1 Common Variant Analysis or Sequencing and/or Deletion/Duplication Analysis~~

ALPHA-1 ANTITRYPSIN DEFICIENCY

SERPINA1 Common Variant Analysis or Sequencing and/or Deletion/Duplication Analysis

I. *SERPINA1* common variant analysis ~~(81332)~~ or sequencing and/or deletion/duplication analysis ~~(81479)~~ to establish a diagnosis of alpha-1 antitrypsin (AAT) deficiency is considered **medically necessary** when:

A. The member/enrollee has any of the following:

1. Abnormally low (less than 120 mg/dL) or borderline (90-140 mg/dL) alpha-1 antitrypsin levels (as measured by nephelometry), **OR**

2. Early-onset emphysema (45 years of age or younger), **OR**

3. Emphysema in the absence of additional risk factor (e.g., smoking, occupational dust exposure), **OR**
4. Emphysema with prominent basilar hyperlucency, **OR**
5. Otherwise unexplained liver disease, **OR**
6. Necrotizing panniculitis, **OR**
7. C-ANCA positive vasculitis (i.e., granulomatosis with polyangiitis), **OR**
8. Bronchiectasis without evident etiology, **OR**
9. A sibling with known AAT deficiency.

II. Current evidence does not support *SERPINA1* common variant analysis ~~(81332)~~ or sequencing and/or deletion/duplication analysis ~~(81479)~~ to establish a diagnosis of alpha-1 antitrypsin deficiency ~~is considered **investigational**~~ for all other indications.

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~~DONOR-DERIVED CELL-FREE DNA FOR LUNG TRANSPLANT REJECTION~~

~~Evidence-Based Donor-Derived Cell-free DNA for Lung Transplant Rejection~~

~~The use of peripheral blood measurement of donor-derived cell-free DNA tests (81479) with sufficient evidence of clinical utility~~view rationale

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CYSTIC FIBROSIS

Diagnostic *CFTR* Sequencing and ~~validity in the management of patients after lung transplantation~~/or Deletion/Duplication Analysis

I. *CFTR* sequencing and/or deletion/duplication analysis to establish or confirm a diagnosis of cystic fibrosis is considered **medically necessary** when:

~~A.~~ The member/enrollee has ~~undergone lung transplantation, **AND**~~

A. ~~The~~a positive (greater than or equal to 60 mmol/L) or inconclusive (30-59 mmol/L) sweat chloride test ~~has not been performed in the last 12 months, AND~~, **OR**

B. The member/enrollee ~~meets at least one of the following:~~has a positive newborn screen for cystic fibrosis as indicated by elevated immunoreactive trypsinogen, **OR**

C. The member/enrollee has ~~clinical signs~~symptoms of cystic fibrosis from at least **TWO** different organ systems:

1. Sinus (e.g. chronic sinusitis, nasal polyps), **OR**
2. Lower respiratory (e.g., bronchiectasis, chronic or recurrent lower airway infection, allergic bronchopulmonary aspergillosis), **OR**
3. Gastrointestinal (GI)/lumen (e.g., meconium ileus, distal intestinal obstruction syndrome, abnormal motility, rectal prolapse), **OR**
4. Gastrointestinal (GI)/hepatobiliary (e.g., pancreatic insufficiency, recurrent pancreatitis, elevated liver enzymes, ecchymosis, cirrhosis, prolonged neonatal jaundice, fat soluble vitamin deficiencies), **OR**
5. Reproductive (e.g., male (sex assigned at birth) infertility because of obstructive azoospermia, female (sex assigned at birth) infertility), **OR**
6. Other symptoms of cystic fibrosis (e.g., hyponatremic dehydration, failure to thrive, pseudo-Bartter syndrome, aquagenic wrinkling of skin, digital clubbing).

II. Current evidence does not support *CFTR* sequencing and/or deletion/duplication analysis to establish or confirm a diagnosis of ~~acute rejection, OR~~cystic fibrosis for all other indications.

~~1. A biopsy was done and is inconclusive for rejection, OR~~

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CFTR Intron 9 PolyT and TG Analysis (previously called Intron 8 polyT/TG Analysis)

I. *CFTR* intron 9 polyT and TG analysis in a member/enrollee is considered **medically necessary** when:

A. The member/enrollee ~~is being monitored for adequate immunosuppression.~~has a diagnosis of cystic fibrosis, **AND**

B. The ~~use of peripheral blood measurement of donor-derived cell-free DNA tests (81479)~~member/enrollee has an R117H variant in the ~~management of patients after lung transplantation is considered~~ ~~**investigational**~~*CFTR* gene.

II. Current evidence does not support *CFTR* intron 9 polyT and TG analysis in a member/enrollee with a diagnosis of cystic fibrosis for all other indications.

~~Emerging Evidence Donor-Derived Cell-free DNA for Lung Transplant Rejection~~

~~I. Donor-derived cell-free DNA tests with insufficient evidence of clinical validity (0118U) in the management of patients after lung transplantation are considered **investigational**.~~

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OTHER COVERED LUNG DISORDERS

Other Covered Lung Disorders

The following is a list of conditions that have a known genetic association. Due to their relative rareness, it may be appropriate to cover these genetic tests to establish or confirm a diagnosis.

I. Genetic testing to establish or confirm one of the following genetic lung disorders to guide management is considered **medically necessary** when the member/enrollee demonstrates clinical ~~features*~~features[1] consistent with the disorder (the list is not meant to be comprehensive, see II below):

A. Familial Pulmonary Fibrosis

B. Primary Ciliary Dyskinesia

C. Pulmonary lymphangioleiomyomatosis (LAM)

D. Pulmonary alveolar proteinosis (PAP)

II. ~~Genetic~~Current evidence does not support enetic testing to establish or confirm the diagnosis of all other lung disorders not specifically discussed within this or another

medical policy will be evaluated by the criteria outlined in the *General Approach to ~~Genetic and Molecular~~Laboratory Testing* (see policy for criteria).

~~*Clinical~~[1]Clinical features for a specific disorder may be outlined in resources such as GeneReviews, OMIM, National Library of Medicine, Genetics Home Reference, or other scholarly source.

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~~BACKGROUND AND~~ back to top

RATIONALE

~~ALPHA-1 ANTITRYPSIN DEFICIENCY~~

~~SERPINA1 Common Variant Analysis or Sequencing and/or Deletion/Duplication Analysis~~

SERPINA1 Common Variant Analysis or Sequencing and/or Deletion/Duplication Analysis

American Thoracic Society and European Respiratory Society

The American Thoracic Society and European Respiratory Society published a joint statement on the diagnosis and management of individuals with alpha-1 antitrypsin deficiency (2003) which provided recommendations for diagnostic testing.

A normal range of plasma alpha-1 antitrypsin (measured via nephelometry) is 83/120 - 200/220 mg/dL. Individuals with borderline normal levels of plasma alpha-1 antitrypsin (90-140 mg/dL) or with abnormally low levels (below 120 mg/dL) should be evaluated for alpha-1 antitrypsin deficiency~~.~~ (p. 826 and 827~~)~~).

"The following features should prompt suspicion by physicians that their patient may be more likely to have AAT deficiency:

- Early-onset emphysema (age of 45 years or less)
- Emphysema in the absence of a recognized risk factor (smoking, occupational dust exposure, etc.)
- Emphysema with prominent basilar hyperlucency
- Otherwise unexplained liver disease

- Necrotizing panniculitis
- Anti-proteinase 3-positive vasculitis (C-ANCA [anti-neutrophil cytoplasmic antibody]-positive vasculitis)
- Family history of any of the following: emphysema, bronchiectasis, liver disease, or panniculitis
- Bronchiectasis without evident etiology…" (p. 820)

The statement also recommended that individuals with a sibling with AAT deficiency should also be offered genetic testing~~.~~ (p. 827~~)~~).

~~**DONOR-DERIVED CELL-FREE DNA FOR LUNG TRANSPLANT REJECTION**~~

~~**Evidence-Based Donor-Derived Cell-free DNA for Lung Transplant Rejection**~~

~~*Centers for Medicare and Medicaid Services*~~

~~The CMS local coverage determination (LCD) entitled "MolDX: Molecular Testing for Solid Organ Allograft Rejection" states the following regarding donor-derived cell-free DNA tests in individuals who have had solid organ transplantation:~~

~~"This Medicare contractor will provide limited coverage for molecular diagnostic tests used in the evaluation and management of patients who have undergone solid organ transplantation. These tests can inform decision making along with standard clinical assessments in their evaluation of organ injury for active rejection (AR).~~

~~These tests may be ordered by qualified physicians considering the diagnosis of AR affiliated with a transplant center, helping to rule in or out this condition when assessing the need for or results of a diagnostic biopsy. They should be considered along with other clinical evaluations and results and may be particularly useful in patients with significant contraindications to invasive procedures.~~

~~The intended use of the test must be:~~

- ~~To assist in the evaluation of adequacy of immunosuppression, wherein a non-invasive or minimally invasive test can be used in lieu of a tissue biopsy in a patient for whom information from a tissue biopsy would be used to make a management decision regarding immunosuppression, OR~~
- ~~As a rule-out test for AR in validated populations of patients with clinical suspicion of rejection with a non-invasive or minimally invasive test to make a clinical decision regarding obtaining a biopsy, OR~~
- ~~For further evaluation of allograft status for the probability of allograft rejection after a physician-assessed pretest, OR~~

- ~~To assess rejection status in patients that have received a biopsy, but the biopsy results are inconclusive or limited by insufficient material."~~

~~*Concert Note*~~

~~For monitoring patients post lung transplantation, absent clear, specific and evidence-based guideline recommendations for a particular regimen of screening, a default frequency of once every 12 months will be adopted.~~

~~**Emerging Evidence Donor-Derived Cell-free DNA for Lung Transplant Rejection**~~

~~Tests that have limited established clinical utility or validity as defined in the Concert policy for General Approach to Genetic and Molecular testing do not meet the threshold for coverage. Evidence for validity may include a Technology Assessment conducted by an independent third party (e.g.MolDx Tech, ECRI, Optum Genomic) and/or evidence-based guidelines published by professional societies. Such evidence was not identified for the tests referenced by this policy.~~

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Diagnostic CFTR Sequencing and/or Deletion/Duplication Analysis

Cystic Fibrosis Foundation

Consensus-based guidelines from the Cystic Fibrosis Foundation (2017) outline the ways in which a CF diagnosis can be established (see below). Characteristic features of CF include chronic sinopulmonary disease (such as persistent infection with characteristic CF pathogens, chronic productive cough, bronchiectasis, airway obstruction, nasal polyps, and digital clubbing), gastrointestinal/nutritional abnormalities (including meconium ileus, pancreatic insufficiency, chronic pancreatitis, liver disease, and failure to thrive), salt loss syndromes, and obstructive azoospermia in males (due to congenital absence of the vas deferens, or CAVD).

These guidelines state that, "Individuals presenting with a positive newborn screen, symptoms of CF, or a positive family history, and sweat chloride values in the intermediate range (30- 59 mmol/L) on 2 separate occasions may have CF. They should be considered for extended *CFTR* gene analysis and/ or *CFTR* functional analysis" (p. S8).

Sosnay et. al

A consensus statement from the 2015 Cystic Fibrosis Foundation Consensus Conference authored by Sosnay et al. (2017) establishes the following as suspicious symptoms for CF in individuals who may not have received screening for cystic fibrosis, or who may have received a false negative NBS test:

Table II. Clinical signs/symptoms that may signify CF (p. S53)

Presenting conditions	Common as first presentation of CF	Uncommon as first presentation of CF*
Family history	Sibling or parent with CF	Parent of a child diagnosed with CF
Sinus	Chronic sinusitis, nasal polyps	
Lower respiratory	Bronchiectasis, chronic or recurrent lower airway infection (especially *Pseudomonas* infection)	ABPA, nontuberculous mycobacterial infection, asthma, chronic obstructive pulmonary disease
GI/lumen	Meconium ileus, distal intestinal obstruction syndrome	Abnormal motility, rectal prolapse
GI/hepatobiliary	Pancreatic insufficiency, recurrent pancreatitis	Elevated liver enzymes, ecchymosis, cirrhosis, prolonged neonatal jaundice, fat soluble vitamin deficiencies (may present as ecchymosis, anemia, edema, night-blindness, skin rash)
Reproductive	Male infertility because of obstructive azoospermia (CBAVD)	Female infertility
Other	Hyponatremic dehydration,failure to thrive	Pseudo-Bartter syndrome, aquagenic wrinkling of skin, digital clubbing

ABPA, allergic bronchopulmonary aspergillosis; GI, gastrointestinal.

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CFTR Intron 9 PolyT and TG Analysis (previously called Intron 8 poly-T/TG Analysis)

American College of Medical Genetics and Genomics (ACMG)

ACMG has recommended that all R117H positive results require reflex testing for the 5T/7T/9T variant in the polythymidine tract at intron 8 in *CFTR* gene. For R117H/5T positive heterozygotes, testing of parents is recommended to determine the inheritance of the R117H and the 5T variant (i.e., cis vs. trans position). For diagnostic testing, and particularly for testing for CBAVD in males with infertility, it is recommended that the intron 8 variant be included in the testing panel (p. 1294).

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Reviews, Revisions, and Approvals	Revision Date	Approval Date	Effective Date
Converted corporate to local policy.	09/23	11/27/23	
Semi-annual review. Updated title to reflect V1.2024 version. Overview, coding, reference-table, background and references updated. Throughout policy: replaced "coverage criteria" with "criteria. For Policy Reference Table: under "SERPINA1 Common Variant…" added "E88.01". For Background and Rationale; under "SERPINA1 Known Familial Variant Analysis: replaced "inheritance patterns" with "genetic testing".	12/23	2/27/24	
Semi-annual review. Updated title to reflect V2.2024 version. In *SERPINA1* Common Variant Analysis or Sequencing and/or Deletion/Duplication Analysis criteria, updated criteria to better align with current guidelines, allowing for an expansion to coverage. In *SERPINA1* Known Familial Variant Analysis criteria, moved criteria to policy "Genetic Testing: General Approach to Genetic and Molecular Testing" to consolidate criteria for known familial variant tests. Minor rewording for clarity throughout. Coding, reference-table, background and references updated.	06/24	9/4/24	10/4/24
Semi-annual review. Updated title to reflect V1.2025 version. Evidence-Based Donor-Derived Cell-free DNA for Lung Transplant Rejection: NEW criteria based on LCD guidelines. Emerging Evidence Donor-Derived Cell-free DNA for Lung Transplant Rejection: NEW Criteria set created for lung cancer diagnostic algorithmic tests for which clinical validity has not been established.	1/25	3/31/25	5/1/25
Annual review. Policy name changed from "Concert Genetic Testing: Lung Disorders" to Concert Genetic Testing: Respiratory. Policy incorporated criteria for CFTR Intron 9 PolyT and TG Analysis (previously called Intron 8 polyT/TG Analysis) and Diagnostic CFTR Sequencing and/or Deletion/Duplication Analysis that was previously in	03/26		

Reviews, Revisions, and Approvals	Revision Date	Approval Date	Effective Date
Concert Genetic Testing: Multisystem Inherited Disorders, Intellectual Disability, and Developmental Delay. "Investigational" policy statements changed to state "current evidence does not support." Policy reference table, rationale, background, coding, and references updated.			

REFERENCES

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2. Deignan JL, Astbury C, Cutting GR, et al. CFTR variant testing: a technical standard of the American College of Medical Genetics and Genomics (ACMG). Genet Med. 2020;22(8):1288-1295. doi:10.1038/s41436-020-0822-5
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~~2.~~5. Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2024. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1116/
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~~4.~~7. MedlinePlus [Internet]. Bethesda (MD): National Library of Medicine (US). Available from: https://medlineplus.gov/genetics/.
~~1. Centers for Medicare & Medicaid Services. Medicare Coverage Database: Local Coverage Determination. MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38582). Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38582~~

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.
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