Driscoll Health Plan
Medical Necessity Guideline

Medical Necessity Guideline: Cystic Fibrosis Carrier Screening-Cystic Fibrosis Transmembrane Conductance Regulator (CFTR)	**Creation Date:** 09/24/2018	**Review Date:** 05/30/2023	**Effective Date:** 11/21/2018

PURPOSE:

To define the requirements and documentation for Cystic Fibrosis Carrier Screening (CPT codes 81220; 81221; 81222, and 81223).

DEFINITIONS:

Cystic Fibrosis Carrier Screening - genetic testing that determines whether an asymptomatic person has a genetic mutation or abnormalities associated with this particular disorder that may be passed on to children. The cause is related to a defect in the gene that produces a protein called cystic fibrosis transmembrane conductance regulator (CFTR). The most common defect is F508 which is approximately 70% of the > 1000 possible mutations. The current screen is limited to this one defect. As a result, about 30% of carrier states are missed. Extended CFTR panels are now available.

Cystic Fibrosis - a hereditary disorder affecting the exocrine glands. It causes the production of abnormally thick mucus, leading to the blockage of the pancreatic ducts, intestines, and bronchi and often resulting in respiratory infection. It affects about one out of every 3,000 newborns. About one in 25 people is a carrier. [1, 2]

GUIDELINE:

Driscoll Health Plan (DHP) requires prior authorization of all requests for Cystic Fibrosis Carrier Screening (CPT codes 81220; 81221; 81222, and 81223). This requirement includes Obstetricians/Gynecologists, Family Practice physicians and Mid-Level practitioners doing Obstetrics.

Documentation requirements:

DHP requires completion and submission of an "OB ATTESTATION FOR CYSTIC FIBROSIS SCREENING" (ATTACHMENT A)**.**

BACKGROUND:

- Cystic fibrosis (CF) carrier screening (CPT 81220, 81221, 81222, and 81223) is a benefit and payable under Texas Medicaid without restrictions.

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- The American College of Obstetrics and Gynecology (ACOG) states that Cystic fibrosis carrier screening be offered to all women due to the pan-ethnicity of the general population. Partner screening should be available if the woman tests positive for the carrier state. (1)
- ACOG recommends screening should be offered to couples prior to pregnancy. (1)
- Patients should be availed of genetic counseling before and after the results of testing. In addition, ACOG underscores the importance of carefully reviewing carrier screening results with patients: "Patients must clearly understand what their results mean to feel empowered and enabled to make informed decisions about their reproductive health or prepare to care for future children. In some instances, this may include referring patients to genetic specialists to ensure they receive education and care tailored to their carrier screening results."
- Cystic Fibrosis Carrier Screening should be limited to once per lifetime. Patients should be advised they have the right to opt-out of genetic screening for this and other conditions. (4)

PROVIDER CLAIMS CODES:

CPT			
81220	81221	81222	81223

REFERENCES:

1. ACOG Committee Opinions, "Carrier Screening in the Age of Genomic Medicine," #690, and "Carrier Screening for Genetic Conditions," #691, March 2017 issue of *Obstetrics and Gynecology*. Reaffirmed 2020., https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/03/carrier-screening-for-genetic-conditions; Accessed 04/30/2021
2. US National Library of Medicine, Genetics Home Reference (2020), Cystic Fibrosis; https://ghr.nlm.nih.gov/condition/cystic-fibrosis, Accessed 05/14/2021.
3. Texas Medicaid Provider Procedures Manual (current edition): Texas Medicaid Fee Schedule
4. Texas Medicaid Provider Procedures Manual, Medical and Nursing Specialists, Physicians, and Physician Assistants Handbook, 5 Geneticists, May 2023.

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DOCUMENT HISTORY:

DHP Committee that Approved	*Review Approval Date (last 5 years)*					
Medical Director	06/13/2019	06/22/2020	06/10/2021 08/03/2021	05/24/2022	06/07/2022	05/30/2023
CMO	06/13/2019	06/22/2020	06/10/2021 08/03/2021	06/07/2022	06/07/2022	06/06/2023
Medical Policy Workgroup *Effective 2022*					06/07/2022	06/06/2023
Medical Management *Retired December 2020*	11/21/2018	06/13/2019	06/22/2020			
Utilization Management & Appeals *Effective January 2021*				06/10/2021 08/03/2021	06/21/2022	06/20/2023
Utilization Management Behavioral Health *Retired December 2020*	11/21/2018	08/22/2019	06/22/2020			
Provider Advisory Committee (PAC) *Effective 2022*					06/17/2022	06/09/2023

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Clinical Management Committee *Effective March 2021*				06/17/2021 09/02/2021	06/24/2022 & 08/23/2022	07/20/2023
Quality Management *Retired 2020*	04/16/2019	10/22/2019	06/26/2020			
Executive Quality Committee *Effective 2021*				08/04/2021 Minor ad hoc revisions only - NA	06/28/2022	07/25/2023

Document Owner	***Organization***	***Department***
Dr. Fred McCurdy, Medical Director	Driscoll Health Plan	Utilization Management

Review/Revision Date	***Review/Revision Information, etc.***
11/19/2018	No changes
11/04/2019	Updated TMPPM reference, Review ACOG literature
05/12/2020	Updated Format, references, ACOG literature is current
06/04/2020	Updated language per Dr. Serrao
05/14/2021	Updated references including ACOG and TMPPM
8/2/2021	Removal of specific laboratories that were named and revised to in network lab
05/13/2022	Reviewed, references updated, minor editing revisions by Dr. Fred McCurdy
05/30/2023	Reviewed by Dr. Fred McCurdy, MD, no changes

Attachment A

- Cystic Fibrosis Carrier Screening should be limited to once per lifetime. Patients should be advised they have the right to opt-out of genetic screening for this and other conditions.

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Cystic Fibrosis Carrier Screening Attestation for OB GYNs
Driscoll Health Plan (DHP) requires prior authorization of all requests for Cystic Fibrosis Carrier Screening (CPT codes 81220, 81221, 81222, and 81223).

Cystic Fibrosis Carrier Screening is genetic testing that determines whether an asymptomatic person has a genetic mutation or abnormalities associated with this particular disorder that may be passed on to children. The cause is related to a defect in the gene that produces a protein called cystic fibrosis transmembrane conductance regulator (CFTR). The most common defect is F508, which is approximately 70% of the > 1000 possible mutations. The current screen is limited to this one defect. Approximately 30% of carrier states are missed. Extended CFTR panels are now available.
Cystic Fibrosis is a hereditary disorder affecting the exocrine glands. It causes the production of abnormally thick mucus, leading to the blockage of the pancreatic ducts, intestines, and bronchi and often resulting in respiratory infection. It affects about one out of every 3,000 newborns. About one in 25 people is a carrier.

DHP Guideline:

- Cystic fibrosis (CF) carrier screening (CPT 81220, 81221, 81222, and 81223) is a benefit and payable under Texas Medicaid without restrictions.
- The American College of Obstetrics and Gynecology (ACOG) states that Cystic fibrosis carrier screening should be offered to all women due to the pan-ethnicity of the general population. In addition, partner screening should be available if the woman tests positive for the carrier state.
- ACOG recommends screening should be offered to couples prior to pregnancy.
- Patients should be availed of genetic counseling prior to and after the results of testing. In addition, ACOG underscores the importance of carefully reviewing carrier-screening results with patients: “Patients must clearly understand what their results mean to feel empowered and enabled to make informed decisions about their reproductive health or prepare to care for future children. In some instances, this may include referring patients to genetic specialists to ensure they receive education and care tailored to their carrier screening results.”

- Cystic Fibrosis Carrier Screening should be limited to once per lifetime. Patients should be advised they have the right to opt out of genetic screening for this and other conditions.

Member Name: _____

Member DOB: _____

Member ID: _____

DHP requires the ordering physician to attest to all of the following for CF carrier screening:

- ☐ To the best of the provider's knowledge, the member has not had Cystic Fibrosis carrier screening before this request.
- ☐ Member has received counseling on genetic screening and informed of his/her ability to opt-out of any and all screening.
- ☐ The provider has the expertise in or timely accessibility to genetic counseling for a member with positive screens.
- ☐ If not performed by an in-network lab, there is medical necessity, unavailability, or other impediments to access to justify referral to another laboratory.

_____ _____

PHYSICIAN SIGNATURE DATE

_____

PHYSICIAN NAME (PRINT)

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